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YOUR FOCUS SEARCH REQUEST IS:

SDI

NUMBER OF STORIES FOUND WITH YOUR FOCUS REQUEST:

6

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April 27, 2000, Thursday

DISTRIBUTION: Business Editors

LENGTH: 2060 words

HEADLINE: Strategic Diagnostics Inc. Announces First Quarter Earnings; Net Revenues Up 47%; Sales Of Seed and

Crop Test Kits Increase 67%

DATELINE: NEWARK, Del., April 27, 2000

BODY:

Development Agreement Signed with Leading Lifescience Organization; New Product Line Acquisition Completed

Strategic Diagnostics Inc. (NASDAQ NM: SDIX) today reported financial results for the first quarter ended March 31, 2000.

Total net revenues increased 47% to \$5,776,000, compared to\$3,919,000 for the comparable period last year. Net income for the first quarter of 2000 was \$304,000, or \$0.02 per diluted share, compared to \$190,000, or \$0.01 per share, before the acquisition-related charge for acquired research and development in the first quarter of 1999. The net loss in the first quarter of 1999 was \$3,310,000, or (\$0.25) per share, including this non-recurring charge. First quarter 2000 net income included \$283,000 of other income attributable to a gain on the sale of the Company's Macra(R) product line, \$127,000 of interest expense associated with the acquisition financing, and income tax expense of \$187,000. The income tax expense is a non-cash expense as it relates to the utilization of the Company's net operating tax-loss carryforwards which have been previously recognized for financial reporting purposes.

The first quarter of 2000 increase in revenues was primarily attributable to increases in agricultural product sales and increased antibody revenues. Agricultural product sales increased due to higher demand for the Company's seed and crop test kits, which increased 67% over the first quarter of 1999. This increased demand was attributable to higher rates of testing to detect the presence of genetically modified traits in seeds and grain, particularly in Brazil and Argentina where, for the first time on a commercial scale, GMO testing and field analysis was utilized to identify GMO/non-GMO grain during the 2000 harvest season. These testing protocols began to be integrated into systems to identify GMO/non-GMO production in the largest soybean producing regions after the United States. Such systems, commonly referred to as "Identity Preservation" or IP systems, are evolving rapidly as participants throughout the agricultural complex devise ways to meet increasing consumer demands for GMO/non GMO products. The Company's analytical test kits for seed and crops are an integral part of such IP systems. The first quarter 2000 revenues also reflect a 173% increase in sales from the Antibody business. This increase was primarily attributable to the inclusion of the revenue from the 1999 acquisitions and to cross-selling synergies realized from the complementary product lines of the integrated businesses. These increases offset decreases in Macra(R) sales and food testing, as anticipated. The Company's Macra(R) product line was sold in the third quarter of 1999 and first quarter 1999 food testing sales included a large order associated with the launch of the product. Product sales in the agricultural category and the antibody business are expected to continue to grow, although at a somewhat more moderate rate.

Agricultural test kit sales are expected to increase as the market for GMO testing and IP systems continues to develop. particularly in the United States, and as SDI continues to develop its relationships within the agricultural biotech industry. As a significant example of the Company's expanding relationships in this industry, SDI has recently signed a diagnostic test development agreement with Dow AgroSciences LLC (DAS), a subsidiary of The Dow Chemical Company. DAS is one of the world's major developers of new genetic traits in plants and crops. The agreement between SDI and DAS provides for the development of laboratory and field test kits for detection of multiple genetically engineered traits that DAS is incorporating into certain crops to impart genetic traits useful to both growers and consumers. The genetic trait test kits, to be developed by SDI, will be used initially for crop breeding and quality control of seed production and will be produced in field and laboratory testing formats.

Gross margins for the first quarter of 2000 were 56.7%, compared with 60.0% in the first quarter of 1999. The reduction is primarily attributable to the mix of revenues between test kit sales and revenues from the antibody business. The revenues of the antibody business produce somewhat lower gross margins than the test kit business.

In another development in the Company's industrial testing category, SDI has completed an Asset Purchase Agreement with Envirol, Inc. of Logan, Utah in April 2000. This agreement constitutes the sale of Envirol's TCE and PCP test kit product line to SDI. TCE is a compound used predominantly in dry-cleaning solvents and materials, and is believed to be carcinogenic. Recently, several states have established environmental funds for the cleanup and monitoring of TCE in groundwater/soil at local dry-cleaning facilities. TCE testing is also required at most Superfund, RCRA and Department of Energy sites for soil and groundwater contamination. SDI is anticipating sales of over \$200,000 for these products in the year 2000.

Richard C. Birkmeyer, President and CEO of SDI, commented, "We are pleased with our first quarter results. In the past, first quarter revenues have been significantly lower than any other quarter in the year. For the first quarter of 2000, revenues were slightly higher than those of the fourth quarter of 1999, reflecting the emergence of our agriculture business and the integration of our antibody business in what historically has been our slowest selling season of the year. We believe the revenue opportunities ahead of us as we approach the 2000 harvest in the United States, as well as incremental revenues from new products coming in through our expanding development pipeline, along with the cross-selling synergies we are beginning to realize in our antibody business, position us well for continued growth."

Mr. Birkmeyer continued, "SDI is currently in the final development and validation stage of additional GMO tests for the other current commercially available traits in corn and anticipates having these tests commercially available in the upcoming weeks. Upon the release of these tests, SDI will have in its product offering a diagnostic test for the detection of every major trait in corn. In an effort to further enhance our market leadership position in both agricultural products and the antibody business, we hired two senior level sales and marketing executives during the quarter. Mr. Nicholas Phillips will serve as the Business Unit Manager for agricultural products, commencing May 2, 2000, and Mr. William Morrison has been appointed Vice President, Sales and Marketing for the Antibody business. The recent transactions also demonstrate our commitment to leadership in all of the markets we serve."

SDI is a leading provider of biotechnology-based diagnostic tests for a broad range of agricultural, industrial and water-treatment applications. Through its antibody business, Strategic BioSolutions, Strategic Diagnostics also provides antibody and immunoreagent research and development services. SDI's test kits are produced in a variety of formats suitable for field and laboratory use, offering advantages of accuracy, cost-effectiveness, portability, and rapid response. Trait Check(TM) is a pending trademark for SDI.

This news release contains forward-looking statements reflecting SDI's current expectation. When used in this press release, the words "anticipate", "enable", "estimate", "intend", "expect", "believe", "potential", "will" and similar expressions as they relate to SDI are intended to identify said forward-looking statements. Investors are cautioned that all forward-looking statements involve risks and uncertainties, which may cause actual results to differ from those anticipated by SDI at this time. Such risks and uncertainties include, without limitation, changes in demand for products, delays in product development, delays in market acceptance of new products, adequate supply of raw materials, inability to obtain required government approvals, modifications of government regulations, modifications to development and sales relationships, the ability to achieve anticipated growth, competition, seasonality, and other factors more fully described in SDI's public filings with the U.S. Securities and Exchange Commission.

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LEVEL 1... 40

Copyright 2001 Gale Group, Inc. ASAP Copyright 2001 Meredith Corporation Successful Farming February 15, 2001

SECTION: No. 3, Vol. 99; Pg. 33; ISSN: 0039-4432

LENGTH: 1879 words

HEADLINE: I-P crops: Mission ImPossible; problems in producing non-genetically modified identity-preserved crops;

Statistical Data Included BYLINE: Holmberg, Mike

Tests show farmers that identity-preserved non-GMO crops are easier said than done

Low (or no) tolerances for genetic contamination in identity-preserved (I-P) crops are like a hidden reef that protects a sandy beech. When the waves of the ocean hit a reef, they create those Hawaii-5-0 waves that skilled surfers dream about. You need to be a skilled surfer if you want to ride those spectacular waves, or you'll wipe out.

That seems to be what is happening with growers trying to ride the wave of interest in identity-preserved grains. Some are enjoying a spectacular ride, while others are being wiped out by the low tolerances for genetically modified crops often included in I-P contracts. The difficulties in meeting these tolerances are creating a great deal of frustration among those trying to produce I-P crops -- and causing many to lose interest.

There are some indications that you will have more opportunities to produce identity-preserved crops in the future. If anti-GMO sentiment builds, you will have opportunities to produce non-GMO I-P crops. If the GMO-furor subsides a bit, you may have opportunities to produce I-P crops with specific output traits.

Whether the premiums offered are attractive enough remains to be seen. Most discussion last year about segregating crops revolved around the amount of premiums for non-OMO crops and whether it would pay to try to segregate non-GMO crops from GMOs. For many, that's still the most important consideration.

Is segregation doable?

There's another big question about increased attempts to produce I-P crops: Can you do it? Segregating GMO and non-GMO crops has been widely criticized as impractical. Last year's StarLink situation-demonstrated how easily contamination can pop up in a supposedly GMO-free crop.

Successful Farming magazine wanted to get a better handle on the practical ability of farmers to segregate I-P crops last year, so we set up a project in central Illinois where I-P crops have been grown for several years. We contracted with Mowers Soil Testing Plus, an independent crop consulting firm, to sample seed from planters in non-GMO fields last spring, then go back to the same fields last fall to collect grain samples from the combines in the same areas.

All of the samples were evaluated for presence of GMOs (Roundup Ready gene in soybeans and Bt in corn) at the Iowa State University (ISU) Seed Laboratory in early December.

We decided to use a bioassay on the soybeans instead of the strip tests used by grain handlers The bioassay determines if the Roundup Ready (RR) gene is present on a seed-by-seed basis so we could calculate a percentage of the sample that would be tolerant to Roundup. Two 200-seed replications were evaluated for each sample.

"Strip tests will only tell you if the Roundup Ready gene is there or not," says Mike Stahr, seed technician at ISU. "It's better to do a bioassay because we can get a percentage."

Each of the com samples was tested for Bt. Since Bt event 176 only shows up in the green tissues, the lab attempted to grow out 400 seedlings from each sample so the leaves could be ground up and tested for Bt. The table below indicates how many leaves were used in the two samples since less than 400 seedlings grew.

The strip tests, mostly supplied by Strategic Diagnostics, Inc., are a "yes" or "no" test, and their sensitivity is determined by the size of the sample. Based on two replications of 200 leaves, SDI claims that two positive tests indicate with 95% certainty that there is more than 1.85% Bt in the sample. Two negative tests indicate that there is less than 0.75% Bt in the sample.

The corn tests didn't produce any big surprises (other than the low germination of the harvest sample from the second field). The first field in the table had both Bt and non-Bt corn planted in the same field. The grower had tried to segregate corn in 1999, but concluded that it wasn't worth the effort. The Bt hybrid was planted first, the planter was emptied, then the non-Bt hybrid was planted.

The results from the third cornfield look like a classic case of pollen drift. With cornfields to the west and north of the non-GMO corn, the harvest sample along the edge of the field was contaminated with Bt. This producer has grown high-oil corn and I-P soybeans before, but this was his first attempt to grow non-GMO corn.

The corn leaves were also tested for the Liberty Link gene, but there were no positive samples from the seed or the harvested grain. The Liberty Link trait must be present in order for StarLink to show up, so the tests indicate that StarLink was not present. Since the time of the study, the USDA has recommended that at least 2,400 seeds be tested for StarLink.

Beans are easier

Most growers believe it is easier to produce I-P soybeans than corn. Soybeans are self-pollinating so there's less chance of pollen drift to contaminate the crop. Soybeans normally aren't dried before storage, which eliminates another potential source of contamination.

We were surprised to find Roundup Ready contamination in several of the soybean samples, but all were within limits of most production contracts. Most non-GMO soybean contracts require samples to have less than 1% RR contamination.

At least one harvest sample on all four non-GMO soybean fields had a low level of RR contamination. Two of the seed samples had low levels of RR seed, which could explain the contamination in those fields. The other two fields had RR seeds in the harvest samples, but not the seed samples.

Re-thinking trust

At the height of last year's discussions about whether it would pay for corn and soybean growers to try to segregate non-GMO crops to capture a premium, some were questioning whether they could buy GMO-free seed. Based on what we found, those were (and are) valid concerns.

"The whole StarLink thing really sets you back in the way you think about your suppliers," says Frank Shafer, Wyoming, Illinois. "Do you trust Pioneer, DeKalb, Asgrow, Garst and the others? I don't know how to answer that question."

```
Soybean samples
        Border crops
                       Sample
                                   RR %
Crop
STS soybean N: Corn/soybean Planter
                                       0.00%
      S: Alfalfa/soybean Harvest-edge 0.00%
      E: Corn/soybean Harvest-middle 0.25%
      W: Corn
                                    0.00%
Non-RR
          N: Sovbean
                         Planter
                        Harvest-edge 0.80%
clean hilum S: Corn
                       Harvest-middle 1.00%
soybean E: Corn
      W: Corn/soybean
STS soybean N: Soybean
                           Planter
                                     0.25%
      S: Corn
                    Harvest-edge 0.25%
      E: Corn
                    Harvest-middle 0.00%
      W: Com
          N: Alfalfa
                                   0.25%
Non-RR
                        Planter
```

```
clear hilum S: Corn
soybean E: Soybean Harvest-middle 0.50%
W: Soybean
```

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Corn samples
```

```
Crop Border crops Sample
                                # leaves Bt strips
                                                      Overall
                       Planter-edge 329
                                                   [greater than]1.85%
Non-GMO N: Soybean
                                               [greater than]1.85%
corn S: Sovbean
                   Planter-middle 387
    E: Soybean
                  Harvest-edge
                                             [greater than]1.85%
                                375
                                        ++
                                              [greater than]1.85%
    W: Bt Corn
                  Harvest-middle 382
                                         ++
                                                [less than]0.75%
                                  373
Non-GMO N: Corn
                      Planter
                                  41
                                         +
corn S: Soybean/corn Harvest
    E: Corn/soybean
    W: Corn
                                                  [less than]0.75%
Non-GMO N: Corn
                      Planter-edge 387
                                               [less than]0.75%
corn S: Soybean
                   Planter-middle 400
    E: Soybean
                  Harvest-edge
                               335
                                             [greater than]1.85%
    W: Corn
                 Harvest-middle 254
                                              [less than]0.75%
Non-GMO N: Corn
                      Planter-edge 391
                                                  [less than]0.75%
                                               [less than]0.75%
corn S: Soybean
                   Planter-middle 365
                                            [less than]0.75%
    E: Corn
                Harvest-edge 322
                                              fless than 10.75%
    W: Corn
                 Harvest-middle 400
```

Seed and harvest samples from eight non-GMO soybean and cornfields were analyzed at the Iowa State University to detect Roundup Ready contamination in soybeans and Bt contamination in the cornfields.

Each soybean sample represents two 200-seed tests. Corn leaves were also divided into two tests for each sample.

Growers plan ahead for I-P crops

Some of the growers who helped in this project hove grown identity-preserved crops for several years. They know what it takes to ovoid contamination.

Tim Green, Wyoming, Illinois, has raised high-oil corn (15% of his acres) for six years and clear-hilum soybeans for the tofu market for 10 years. The tofu varieties and non-GMO beans comprise about 60% of his bean acres.

"When I plant the corn, I try to clean out the planter thoroughly. Then we try to harvest it in one shot so the combine isn't going back and forth between fields, but is kept pure all the time. We have a specific bin site we use only for high-oil corn. The bins have only had high-oil corn in them the last four years, so it's a little easier to avoid contamination," Green says.

"The clear-hilum beans are earlier varieties, so all my regular beans and Roundup Ready varieties are planted at the normal time. I clean out the planter and plant the clear-hilum beans last.

No rejects

"The early beans are ready first. so I cut my non-GMO and P beans before I cut anything else." Green says. "My combine has non-GMO beans in it prior to cutting the tofu beans. I don't have to worry about contamination, and that's worked out pretty good. This year all my non-GMO beans went through as non-GMO. They were testing every load, and I didn't have a load rejected."

Pete Gill, Bradford, Illinois, says they didn't worry about buffers with high-oil corn, but they did leave a 60-foot buffer strip along the edge of their non-GMO corn.

"The field ahead of the non-GMO corn was not Bt, so we used that as a flush for the combine. We stored it in a bin where there wouldn't be any corn spilling into it from the grain leg," Gill says.

DATE: NOVEMBER 8, 2001

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YOUR FOCUS SEARCH REQUEST IS: GMO OR NON-GMO

NUMBER OF STORIES FOUND WITH YOUR FOCUS REQUEST:

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- 5. Business Wire, January 18, 2001, Thursday, 806 words, Strategic Diagnostics Releases Preliminary Fourth Quarter Results; Fourth Quarter Revenue Expected to be 51% over 1999 Period, Jan. 18, 2001
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- 13. Business Wire, January 5, 2000, Wednesday, 1677 words, Strategic Diagnostics Inc. Announces the Completion of Its Test Kits for the Detection of Bt Cry1A -b- in Corn and Announces Preliminary Results for 1999, NEWARK, Delaware, Jan. 5, 2000
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March 13, 2000

SECTION: No. 11, Vol. 257; Pg. 22; ISSN: 1092-0110

LENGTH: 1065 words

HEADLINE: Controversy Over Biotechnology Creates Opportunities for Diagnostics; companies seeks diagnostics to ensure their products are free of genetically modified ingredients; Brief Article

BYLINE: PAPANIKOLAW, JIM

BODY:

THE IMPACT of biotechnology on agriculture and the debate over genetically modified organisms (GMOs) is expected to fuel the need to test for genetically enhanced traits in crops, creating new markets for diagnostic tests. Protein and DNA tests are already used for soil and water quality control, in healthcare and to develop GMOs.

Most of the GMO products that have achieved impressive market penetration in the US and Canada feature input traits--genetically enhanced resistance to pests and herbicides. But those GMOs are facing a backlash in Europe and the Pacific Rim from environmental and consumer groups concerned about potential side effects on the ecosystem and human health.

The debate about GMOs continues, but in early February, industry and environmentalists reached an international accord, the Biosaftey Protocol, in Montreal. That treaty, which is expected to take at least two years to be ratified, calls for the labeling of bulk shipments of commodities that "may contain" GM varieties.

The next wave of GMOs are expected to contain enhanced nutritional qualities (output traits). Although segregation, which is not required under the current version of the Biosaftey Protocol, may not be considered economically desirable for input trait varieties, companies marketing output trait varieties may want to separate their value-enhanced products from cheaper non-GMO strains.

Analysts expect these advances to drive a need for GMO tests that are cheap, quick, easy and reliable.

"We foresee a chain-of-custody approach to testing, where virtually every participant in the seed-to-table process will want to prove the genetic identity of the product for which it is responsible," explains Maria Wimmer, an analyst for Deutsche Bane Alex Brown.

"Seed producers will test seeds, farmers will test grain, elevator operators will test as they buy the grain. For export product, grain will likely be tested at both the port of entry and the port of embarkation. And finally, the processor of the grain of oilseed will test both as the grain enters the gate, and again, providing a certificate of purity as the food fraction is sold to the packaged-foods manufacturer."

Deutsche Banc projects that over the next five years, revenues from GMO tests could reach \$950 million. Ms. Wimmer notes that none of the specific business opportunities is guaranteed to grow as forecasted, but the range of opportunities makes the market promising.

The basic technology in protein tests is usually antibodies--proteins produced by the immune system to specifically bind to a foreign invader (antigen). The formats for these tests include a well-plate immunoassay and a simple color

strip test. Generally, the plate tests can determine antigenic concentrations, but they are restricted to the lab and are for ground up grains and oilseeds. The color strips test for antigens in whole seeds and can be used anywhere.

The more a GM grain or oilseed is processed, the harder it is for tests, protein or DNA, to detect GMO traits. However, the industry says this indicates that the proteins and DNA from the GMOs are denatured during the processing steps, many of which include heat treatment.

Companies have been able to determine the presence of minute concentrations of molecules, including chemical toxins, infectious agents and proteins found specifically in GMOs. Analysts emphasize that crops can incorporate many types of genetically enhanced traits. Different proteins in unrelated crops can also produce the same genetic traits. Analysts expect this diversity to lead to an array of products and players.

Newark, Del.-based Strategic Diagnostics Inc. (SDI) was formed in 1990 and originally developed protein tests for water quality, soil remediation and medical purposes, although the company's overall strategy is to pursue any market that requires an assay.

The company's involvement in the GMO test market started by manufacturing such kits under a private label for ag biotech and seed companies to use in selective breeding and quality control during seed development.

SDI's first commercially available product for this market was a test for Monsanto's Roundup herbicide-resistance trait RoundupReady in soybeans. The company also offers tests for the pest-resistance trait in Bt (Bacillus thuringiensis) corn. Tests for AgrEvo's (now Aventis) Liberty herbicide-resistance trait LibertyLink are also close to market.

The company's current tests are for input traits, but SDI also plans to develop and market output trait tests as those crops emerge commercially.

SDI's net revenues totaled \$22.5 million in 1998. The company's stated financial goal is to reach \$100 million in sales in three to five years--a minimum of a 48 percent compound annual growth rate from 1998 revenue.

Portland, Me.-based Envirologix develops, manufactures and markets immunoassays to detect water toxins and pesticides, and it offers a custom immunoassay development. About two years ago, the company first saw the market potential for protein tests for GMO traits.

The company offers kits for detecting certain Bt proteins in corn and cotton. Additional tests for other Bt proteins and the RoundupReady trait are in progress. The company recently signed a licensing agreement with Aventis to develop tests for the LibertyLink and StarLink traits for herbicide and pest resistance, respectively.

Other companies that are developing or marketing GMO-trait protein tests include Brookings, S.D.-based Mid-West Seed Services Inc.; Freiburg, Germany-based GeneScan Europe AG (also DNA tests); and Nellies Gate, Auchincruive, UK-based Adgen Ltd.

DNA GMO tests typically consist of polymerase chain reaction technology, which involves making multiple copies of a trace amount of genetic material for screening. Such assays can be used in nearly any case involving genetic material, including quality control, forensics and GMO testing. Analysts note that DNA assays may be more sensitive than protein tests, but they are more expensive and time consuming.

Companies either developing or marketing DNA tests include Balgach, Switzerland-based Microsynth GmbH; Cedex, France-based AgroGene SA; Belle Chasse, La.-based Central-Hanse Analytical Laboratory; Saint Beauzire, France-based Genolife; and Berlin, Germany-based BioteCon GmbH.

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HEADLINE: Strategic Diagnostics Inc. Announces the Completion of Its Test Kits for the Detection of Bt Cryl A -b- in

Corn and Announces Preliminary Results for 1999 DATELINE: NEWARK, Delaware, Jan. 5, 2000

BODY:

Strategic Diagnostics Inc. (NASDAQ: SDIX) today announced that their Bt Cry1A(b) corn test kits are in the final stages of customer validation.

Kits are being shipped to key customers for final evaluation and validation with initial response exceeding expectations. Initial orders are now being taken and the official commercial launch of the two test kits is expected to occur in January 2000. Both kits utilize an immunodiagnostic test strip developed by SDI that provides users with a rapid, easy-to-use test that gives a definitive result in under five minutes. The tests can be used as a rapid screening tool for the detection of Bt Cry1A(b) in corn to levels of 0.5% for Bt11 (a product of Novartis) and MON 810 (a product of Monsanto). Test validation has shown the test to be greater than 99% accurate.

The first test has been developed for seed licensees to assure the high quality of seeds grown by foundation seed growers for sale to commercial growers and can be used for all Bt Cry1A(b). The second test is designed for the grain industry to identify the genetic traits in corn and will be distributed through SDI's partnership with AIT (Agricultural Information Technology). AIT provides key components of an Identity Preserved System for input and output traits in seed, crop, grain and food products. The Postmark (TM) line of products assists businesses in effectively tracking agricultural materials. The Postmark brand products include SIGNPOST (TM), an onsite field marking system, SEEDTAG (TM), a comprehensive database of seed traits for corn, soybeans, and cotton and CROPTOUCH (TM), a process and materials tracking system. AIT, in affiliation with its distribution partners, which include United Agri-Products and Cenex, has over 1,000 sales representatives throughout the world.

Tim Aughenbaugh, President and CEO of AIT commented, "AIT is excited to expand the relationship with SDI and in doing so, be able to better serve the agricultural industry as it increases its focus on the traceability of agricultural materials. This expanded strategic relationship with SDI will allow AIT to maintain a leading role as the industry's provider of "agricultural identity preservation systems."

These tests for corn were modeled after the Trait Roundup Ready(R) test released earlier this year for the detection of Roundup Ready(R) soybeans. This test has been commercially successful as a rapid tool in the identification and separation of soybeans according to genetic composition. The test, when used with an appropriate sampling plan, is being used to separate soybeans below defined thresholds (0.5% - 5%). Food fractions derived from separated soybeans are then tested with SDI's GMO test as a quantitative means for food processors to comply with labeling requirements in many parts of the world including the European Union and Japan. The GMO test was validated in a European Ring study in December 1998. Monsanto and SDI are currently validating a similar GMO assay for Bt Cry1A(b) in corn.

The grain and food distribution segments in agriculture have expressed significant need for this analytical technology to meet market requirements to identify genetically modified corn in world markets. This need has developed rapidly. U.S. producers have increasingly adopted the genetic technology after the success they experienced in the 1998 and 1999 growing seasons. The U.S. Department of Agriculture estimated that approximately 30% of the 9.7 billion bushels of U.S. corn produced in 1999 incorporated genetic technology and industry reports of early indications for the 2000 growing season show that utilization of this technology may decline from the 1999 level but will still remain an important tool for commercial growers. The growth in the need for SDI's products has been the promulgation of labeling regulations adopted in many regions of the world including the two largest agricultural commodity-trading partners, the European Union and Japan. These labeling requirements have required or are expected to require food processors to label finished food products as to the genetic composition of the ingredients used to produce these products.

The initiation of labeling and the growing number of food processors electing to use non-GMO raw materials are driving the need for identity preservation. The SDI test has become the standard in the grain distribution market. However, as many food companies delayed implementing labeling and the use of non-GMO source material, the demand for identity preserved raw material was lower than anticipated by many of the earlier adopters of SDI's test. Therefore, reorders that were anticipated by these early adopters did not materialize in the fourth quarter. Consequently, the Company expects revenues to be approximately \$5.8 million for the fourth quarter of 1999 (a 60% increase over its fourth quarter 1998) and \$22.6 million for the full year (a 44% increase over 1998 full year revenues). The Company anticipates earnings before taxes (excluding the \$3.5 million charge for in-process research and development expenses related to a first quarter 1999 acquisition) to be approximately \$450,000 (or \$0.03 per diluted share) for the fourth quarter of 1999 and \$2.0 million (or\$0.11 per diluted share) for the full year. These estimated results compare with fourth quarter 1998 revenues of \$3.6 million and a loss of \$450,000 or \$0.03 per share. These anticipated results for 1999 however are lower than analysts estimates of \$7.6 million in fourth quarter revenues and \$1.1 million (or \$0.07 per diluted share) of fourth quarter pre tax earnings and \$24.5 million of full year revenues and \$2.7 million (or \$0.16 per diluted share) of pre tax income for the full year.

The market for the Company's agricultural products continues to develop. Labeling specifications are nearing completion in both Europe and Japan. Identifying the genetic composition of grain and commercial crops and maintaining that identity throughout the agricultural complex to support labeling has become a high priority for seed companies, commercial growers, distribution and processing companies, as well as food processors during 1999 and is expected to increase as labeling is further implemented in 2000. SDI offers leading products in each of these emerging markets. The rate at which prospective customers adopt and implement testing protocols and procedures throughout the world is expected to continue to have a significant impact on sales of the Company's products. The Company has indications of interest for purchasing substantial quantities of the Company's products from prospective customers throughout the world, and particularly the United States, Europe and Japan. Delays in establishing technical labeling definitions delayed the timing of orders for the company products. As a result of this additional experience with these developing markets particularly in agriculture, the Company anticipates first quarter 2000 revenues to grow in the range of 45% - 55% over 1999 first quarter revenues. Income before income taxes for the first quarter of 2000 is expected to be in the range of 8% - 10% of revenues.

Richard C. Birkmeyer, President and CEO of SDI commented, "We are excited to have a product that can meet the customer need in the grain market for identity preservation. The 0.5% sensitivity in under 5 minutes was a challenge that we met. Our test also detects Cry 1A(b) in all three commercial events, Mon 810, BT11 and Event 176. This assay is the only analytical tool for corn that meets the market requirements of the grain distribution industry for sensitivity and timing. This challenge of validating our test kits within an Identity Preservation system that would be accepted by the end user as well as establishing the distribution for this product delayed the release of this product slightly. However, we believe it is critical to fully validate the use of the tests for market-driven applications for the long-term success of GMO testing. We believe that the availability of these tools will provide consumers with a choice and is expected to stimulate broad acceptance of GMOs."

SDI is a leading provider of biotechnology-based diagnostic tests for a broad range of agricultural, industrial and water-treatment applications. Through its antibody business, Strategic BioSolutions, Strategic Diagnostics also provides antibody and immunoreagent research and development services. SDI's test kits are produced in a variety of formats suitable for field and laboratory use, offering advantages of accuracy, cost-effectiveness, portability, and rapid response. Trait Check (TM) is a pending trademark for SDI.

This news release contains forward-looking statements reflecting SDI's current expectation. When used in this press release, the words "anticipate," "enable", "estimate", "intend", "expect", "believe", "potential", "will" and similar expressions as they relate to SDI are intended to identify said forward-looking statements. Investors are cautioned that all forward-looking statements involve risks and uncertainties, which may cause actual results to differ from those anticipated by SDI at this time. Such risks and uncertainties include, without limitation, changes in demand for products, delays in product development, delays in market acceptance of new products, inability to obtain required government approvals, modifications of government regulations, modifications to development and sales relationships, the ability to achieve anticipated growth, competition, seasonally, and other factors more fully described in SDI's public filings with the U.S. Securities and Exchange Commission.

CONTACT: Strategic Diagnostics Inc., Arthur A. Koch, Jr., Chief Operating Officer, 302/456-6789, http://www.sdix.com or Lippert/Heilshorn Associates, Inc., IR, John Nesbett/Vince Daniels 212/838-3777

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SECTION: FLAVORS AND ENHANCERS; Vol. 7, No. 5

LENGTH: 645 words

HEADLINE: Tests for Genetically Modified Traits

BODY:

Strategic Diagnostics, Inc. (SDI, 111 Pencader Dr., Newark, DE 19702; Tel: 302/456-6789) has entered into agreements to distribute and develop immunoassay tests to detect genetically modified organisms (GMOs). The distribution agreement is for its soya food testing kit, and was made with Gene Scan Europe, which is the outcome of a merger of four biotech companies in Germany: BIG Biotech GmbH, BioChip Technologies GmbH, GENESCAN GmbH, and Hanse Analytik GmbH. The agreement gives GeneScan the exclusive distribution rights for the test kits within Germany, and on a non-exclusive basis throughout the other EU countries with the exception of the U.K.

The SDI rapid test kit allows for the full range of GMO testing: quantitative determination of genetically modified organisms in raw agricultural commodity such as in soybeans, and food fractions such as in flour or protein concentrate. The company has a polymerase chain reaction (PCR) assay for testing finished food products.

The soya test kit detects the presence of Monsanto's Roundup Ready herbicide- tolerant trait in soya food ingredients. Underway, is the development of a maize test kit, which will detect Monsanto's YieldGard insect-protected trait in corn- based ingredients. SDI plans to introduce six more trait test kits for seeds in 1999, and more in 2000.

The test will be part of a multi-trait test kit that will detect all the genetically modified traits that have been approved in the EU. This will help food processors in the EU conform with recent labeling regulations requiring them to label foods containing ingredients derived from GMOs.

On the domestic side, SDI has entered into diagnostic test and development and licensing agreements with Monsanto Agricultural Co. (800 N. Lindbergh Blvd., St. Louis, MO 63141; Tel: 314/694-1000). The tests will detect the presence of genetically modified traits in crops that may have been used as food ingredients. Under the agreement, Monsanto is licensing the use of its proprietary technology to SDI for the manufacture and sale of these test kits to food processors, their suppliers, and regulatory bodies responsible for overseeing the labeling of these products.

SDI has begun to reap benefits from the soya tests, reporting that agricultural products sales increased 270% for the first quarter ending March 31. Total net revenues increased 35% to \$3,919,000 compared to \$2,896,000 for the comparable period last year. The increase in revenues was primarily driven by the increase in agricultural sales, which included test kit sales for traditional seed testing as well as the first shipments of the new test kits to detect the presence of genetic traits in food fractions.

Briefly Noted:

- * As if the current problems with pathogens such as listeria and E. coli aren't enough to cause concern in the food processing industry, Emerging Infectious Diseases [5(1), 1999], published by the Atlanta-based Centers for Disease Control and Prevention, has reported that Campylobacter jejuni is an emerging foodborne pathogen. The article says that Campylobacter jejuni is the most commonly reported bacterial cause of foodborne infection in the nation, and is now the leading cause of bacterial gastroenteritis reported in the U.S. Campylobacteriosis was followed in prevalence by salmonellosis (28%), shigellosis (17%), and Escherichia coli O157 infection (5%).
- * The USDA is establishing about \$2 million for research into the safety of ready-to-eat foods. The move was promoted by the recent recalls of foods contaminated by bacteria. Research will help to determine the risks of uncooked foods, and such ready-to-eat foods as deli meats. The funding is part of the \$4.7 million earmarked to study ways to prevent foodborne illness from such foods as imported fruits and vegetables, processed foods and ready-to-eat foods.



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Strategic Diagnostics receives USDA verification of new SDI TraitCheck Bt9 lateral flow strip test

Newark, New Jersey January 18, 2001

Strategic Diagnostics, Inc. (NASDAQ: SDIX) - a leading provider of analytical test kits for the agricultural, water quality and food testing markets, today reported that the USDA Grain Inspection, Packers and Stockyards Administration (GIPSA) recently certified a new SDI TraitCheck Bt9 Lateral Flow Test Strip with detection limits of one StarLink(TM) corn kernel in 800 non-StarLink(TM) kernels (0.125%) in less than 10 minutes.

The test strip had previously been validated at the 400 kernel testing level. The USDA and FDA have recently established a 2,400 kernel sampling guideline to detect StarLink(TM) corn contamination in the US grain distribution system. The new sensitivity will require only three samples to be tested, which has been the prior practice before the FDA guidelines were issued. GIPSA will update its directive of official StarLink(TM) testing methods to include this new performance validation. With this development, SDI continues to be the leader in GMO testing.

To complement the new TraitCheck Bt9 Test Strip, SDI has also introduced the GMO QuickCheck Bt9 Test Kit. The Company believes this rapid ELISA microwell format is ideal for field confirmation of screening results for the Cry9C protein. With the plate format, up to 14 samples can be analyzed at one time with results in less than 15 minutes. The ability to analyze multiple samples in a less than 15 minutes makes this test kit an excellent confirmatory method when used in conjunction with the TraitCheck Bt9 Test Strip. The GMO QuickCheck Bt9 Test Kit is currently undergoing validation by the USDA GIPSA.

In another new product introduction, SDI has completed validation of an improved GMO Check RUR Soya Test Kit. This ELISA-based method can detect the presence of Roundup Ready(R) soybeans in processed soya products used in the food and animal feed industries such as flours, de-fatted flakes, protein isolates, protein concentrates, soymilk, tofu and toasted meal as low as 0.1%. Unlike the previously released version of this product, the ability to detect the RUR protein in highly processed soy products is very unique and represents a significant technical achievement. The introduction of this product is also very timely given the European Union's (EU) concern over bovine spongiform encephalopathy (BSE), or mad cow disease, and their move away from animal bone meal feeds to toasted soy meal animal feeds. Animal feed products are regulated under the EU GMO guidelines.

Richard C. Birkmeyer, President and CEO of SDI commented, "The current concern around GMO testing has created a unique opportunity for Strategic Diagnostics and we feel we have been recognized by the industry as the leader in comprehensive analytical methods for the testing of GMO's. SDI has strong relationships within the agricultural biotechnology, seed and grain industries. We have developed strip tests and ELISA methods for all major traits currently in commercial production, including Roundup Ready(R), Liberty Link(TM), Bt Cry 1Ab and Bt Cry 9C, all as a result of these relationships. We believe SDI is the only company to provide lateral flow testing products for all of these traits. We have demonstrated that our tests work in most major crops, including corn, soybeans, cotton and canola. Through the effective leveraging of these relationships, we are developing tests for the next round of GM crops with two more to be introduced in this quarter."

Mr. Birkmeyer continued, "We have focused our efforts on providing the industry with the appropriate tools available for testing, along with the proper training on the usage of these tools, as we feel the best advertisement is to have customers and regulatory agencies incorporating our test kits into policy and practice. Toward this end, we feel that it is critical to focus our efforts on promoting the features and benefits of our tests within the industry, since this ultimately sells test kits. The industry has recognized the efficacy of our testing products, and in the last two years has utilized more than 8,000,000 lateral flow strips, establishing us as the clear market leader."

SDI is a leading provider of biotechnology-based diagnostic tests for a broad range of agricultural, industrial, and water treatment applications. Through its antibody business, Strategic BioSolutions, Strategic Diagnostics also provides antibody and immunoreagent research and development services. SDI's test kits are produced in a variety of formats suitable for field and laboratory use, offering advantages of accuracy, cost-effectiveness, portability, and rapid response. Trait Check (TM), GMO QuickCheck(TM), and GMO Check(TM) are pending trademarks for SDI.

Company news release



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GM CROP TESTING GROWS AMID CONTROVERSY

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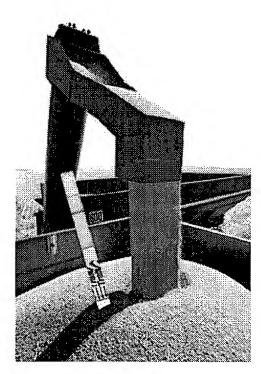
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Hot Articles

James W. Stave and Donald Durandetta

New diagnostics track the identity of agricultural products.



The efforts of agricultural biotechnologists have resulted in commercial crops such as corn and soybean with new agronomic traits. This has been accomplished by taking novel pieces of DNA and inserting them into plants in a way that causes production of proteins that confer beneficial characteristics to the plant. The first wave of such crops all have traits that directly benefit farmers, including resistance to insects and herbicides. Genetically modified crops were introduced throughout the 1990s in the United States and have been rapidly adopted by the market segment they were intended to benefit, that is, the farmers. Indeed, in 1999, approximately half of the soybean and one-third of the corn crop in the United States was the product of agricultural biotechnology, and worldwide production of these crops is increasing rapidly (1).

Novel DNA and protein can be found to varying degrees in many parts of the modified plants, including seeds and grain, and the processed fractions and final foods prepared from them. While farmers in general have recognized the value of these first-generation agbiotech crops, consumers do not necessarily perceive a direct benefit to themselves. A general sense of anxiousness exists about any activity that could be viewed as "tampering" with the food supply. Especially in Europe, where there have been several scares related to the food supply in recent years, there is strong sentiment against the use of agbiotech crops for production of food and animal feed (2).

Companies developing agbiotech crops carry out extensive testing to demonstrate such things as safety and environmental impact, as well as agronomic performance, before commercialization. The data from these studies are reviewed by government

authorities who must grant approval before the crop can be sold. Many such crops have already been granted approval for use in food and feed by governments all over the world. While there is general scientific consensus that foods derived from agbiotech crops do not pose human health concerns beyond those that are present in existing foods, loud voices within society, primarily consumer and environmental groups, have questioned whether the extent of testing is sufficient.

In addition to food safety concerns, many environmental groups have questioned whether the new genes inserted into these plants may find their way into other closely related plants and lead to unexpected and undesirable effects on the environment (3). Still other concerns have been raised about the effect that large-scale cultivation of a relatively limited number of varieties, representing a limited gene pool, may have on biological diversity throughout the world (4). The controversy surrounding agbiotech crops has left consumers confused and uncertain about the issues.

Laws for labeling

Many believe that if governments, scientists, industry, and consumer groups can't come to a consensus regarding the overall safety of agbiotech, then consumers should be given the right to decide for themselves whether to eat foods containing agbiotech ingredients. As a result, several countries, including the European Union and Japan, have passed laws requiring that foods containing agbiotech ingredients be labeled as such.

An important aspect of these laws is the inclusion of a minimum threshold concentration. If a food contains agbiotech ingredients above the minimum threshold, the food needs to be labeled. Because the approved crops have already been determined to be safe for human consumption, the existence of a small percentage of an agbiotech ingredient below the threshold concentration has been determined to be an issue of commerce and international trade, rather than a safety issue.

For example, there is general recognition that when dealing with large containers filled with grain (elevators, barges, ships, etc.), it is impossible to prevent incidental commingling of the contents with material left in the container from the previous use. Existing international trade practices currently make allowances for incidental carryover between shipments. On the basis of similar considerations, food labeling laws incorporate the concept of a minimum threshold concentration. It is reasoned that foods that may contain agbiotech ingredients at concentrations less than the specified threshold, for example, because of incidental carryover during shipment, would not be labeled.

The explosive introduction and large-scale production of agbiotech crops, coupled with the adoption of food-labeling laws, have left farmers, grain import—export companies, food processors and retailers, and regulatory enforcement agencies scrambling to implement food labeling.

Identifying Crops

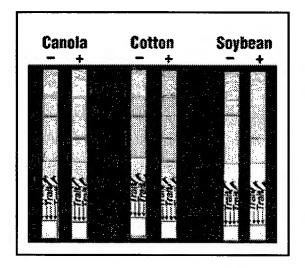
One way to know whether an ingredient is derived from an agbiotech crop is to establish the identity of the material at its origin and to trace its identity from planting through harvest, distribution, processing, and labeling in a way that preserves the identity of a product throughout the entire process. Current agricultural, distribution, and trade practices are not compatible with such a system. However, the entire industry recognizes that when the second wave of agbiotech products are commercialized—those containing traits valued by consumers (e.g., enhanced nutritional content)—identity-preservation systems will be necessary to tout and guarantee the added value of these crops. Industry, therefore, is already making plans to implement identity-preservation systems.

An alternative approach for determining whether a food contains ingredients derived from agbiotech crops is to check a representative sample for novel DNA or its resulting protein. The quantity of agbiotech crop in the food is then determined by extrapolation from the sample's results. An inherent difficulty with this approach is that the analytical techniques measure protein or DNA, but the laws mandate labeling based on the percentage of genetically modified organisms (GMO) present in an ingredient. The definition of %GMO is crucial to determining concentrations and is operationally defined as the percentage of positive beans, kernels, seeds, or

other discrete units present in a pool of non-GMO units. For example, 1 GMO soybean mixed with 99 non-GMO beans represents a 1% GMO. Europe has currently established a 1% GMO threshold with respect to food labeling, and Japan has established a 5% threshold.

To support labeling, a measurement technique must be able to determine whether the concentration of GMO in the sample is above or below the mandated threshold concentration with some specified level of confidence, accuracy, and precision. Techniques are available for detecting both proteins and nucleic acids, and their relative merits are the subject of considerable scientific debate (5, 6). It is possible to detect the novel DNA sequences present in agbiotech crops and ingredients using techniques such as the polymerase chain reaction (PCR). A PCR method for detecting the CP4 EPSPS gene, which confers resistance to the herbicide Roundup, was evaluated in a European Ring Study organized by the Joint Research Centre (JRC) of the European Union (7). The study findings demonstrated that the PCR method could detect the CP4 EPSPS gene, but only qualitatively. Thus, the method was not suitable for use in determining whether a sample contained GMO above or below a mandated threshold concentration.

Novel proteins can be detected in agbiotech crops and processed food fractions using immunoassavs. Like PCR, an enzyme-linked immunosorbent assay (ELISA) that detects the CP4 EPSPS protein was also evaluated in a European Ring Study by the JRC (8). The test protocol was designed to determine themethod's capability of distinguishing whether a sample contained GMO above or below an arbitrary threshold of 2%. The findings demonstrated that the samples identified as negative by the test contained less than 2%



Detection of CP4 EPSPS in the seeds of different crops.

GMO, and samples that scored positive contained at least 0.85% GMO with a confidence of 99%. The within-laboratory repeatability was $\pm 7\%$, and the reproducibility between laboratories was $\pm 10\%$. Although the test was designed specifically to determine whether a sample was above or below a specified threshold, the data clearly demonstrated that the test could be used to determine GMO concentration quantitatively.

Realistic Tests

The utility of any testing method is ultimately limited by the nature of the specific application. Because of technical as well as practical considerations, food processors have not implemented large-scale testing programs to determine GMO concentrations in support of labeling. Instead, they have pushed the burden back on their raw material suppliers, the grain distribution system. Without question, the most critical point of monitoring in the grain distribution system is at the initial point of sale, that is, when the producer sells to the local elevator. As larger pools of grain are created, it becomes increasingly difficult and costly to acquire and analyze enough samples to get an accurate representation of the distribution of grain in a container.

The majority of grain is harvested during a frenzied period of time, typically two weeks, in which trucks are standing in line at elevators and moving through the system at a rate of about one every five minutes. Grain as a commodity cannot support much in the way of additional costs associated with testing. Under these conditions, it is critical to test grain immediately, on-site, at very low cost per sample,

and the assay must be simple to use. Quantitative PCR is a highly complex procedure, requires expensive instrumentation and laboratory facilities, costs anywhere from \$400 to \$700 per sample, and routinely takes 3–10 days to get a result. Although ELISA methods require only one to four hours to perform and cost one-tenth as much, they still are not ideal for truck-side testing.

Another form of immunoassay, the immunochromatographic strip test, has been developed to meet the performance specifications required for testing agbiotech crops in the field (see box, "Strip Tests" for AgBiotech Proteins). These tests use the same technology as the home pregnancy test. They are very easy to use, cost less than \$10 per test, take 5–10 minutes to complete, and can be performed truck-side.

For the foreseeable future, agbiotech crops will coexist with conventional varieties, and the world will have to find ways to deal with both. Coupling the advent of agbiotech crops with consumer-valued traits will necessitate that systems and strategies capable of preserving the identity of these crops be in place to capture the added value, work that is done now to develop these systems will facilitate commercialization in the future. Although detection technology is available for most agbiotech crops, implementation of testing lags behind production and regulations, leaving the entire industry in a quandary on how to proceed. In the near term, it seems likely that solutions will comprise elements of identity preservation, incorporating screening tests at critical control points throughout the distribution system along with limited, standardized testing at major points of export and import

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James W. Stave is vice president of research and development for Strategic Diagnostics Inc. (Newark, DE). Donald Durandetta is a product manager for agricultural products for Strategic Diagnostics Inc. (Newark, DE). Comments and questions for the author can be addressed to the Editorial Officeby e-mail at tcaw@acs.org, by fax at 202-776-8166 or by post at 1155 16th Street, NW; Washington, DC 20036.

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STRATEGIC DIAGNOSTICS REPORTS THIRD QUARTER RESULTS

USDA Verifies Cry9C Test Kit Performance

NEWARK, DELAWARE, OCTOBER 26, 2000 - STRATEGIC DIAGNOSTICS INC. (NASDAQ: SDIX) - a leading provider of analytical test kits for the agricultural, water quality and food testing markets, today reported financial results for the third quarter ended September 30, 2000. Net revenues were \$5.7 million, versus \$7.5 million in the third quarter of 1999, a decrease of 24%. As previously reported, the decrease in revenues was primarily attributable to shortfalls in purchases of the Company's agricultural products and certain products in the industrial category being de-emphasized. The shortfalls were primarily attributable to the market for the Company's agricultural test kits developing more slowly than previously anticipated. The decreases described above offset increases in the Company's antibody business, which grew 16% in the third quarter of 2000 to \$2.7 million. Operating income for the third quarter of 2000 was \$281 thousand versus \$1.2 million in the prior year. Net income was \$89 thousand or \$0.01 per diluted share compared to \$1.0 million in the third quarter of 1999 or \$0.06 per diluted share.

For the nine months ended September 30, 2000, net revenues were \$17.3 million, versus \$16.9 million in the prior year, an increase of 2%. Operating income for the nine-month period was \$1.1 million versus \$1.7 million in the prior year. Net income for the 2000 nine-month period was \$659 thousand or \$0.04 per diluted share versus \$1.5 million or \$0.09 per diluted share (1999 operating and net income are before a one-time acquisition charge for in-process research and development of \$3.5 million).

Significant changes in general affecting the volume of analytical testing are currently occurring throughout the agricultural complex in response to StarLink TM corn, which contains a trait not approved for food use,



allegedly entering into food production. While the full effects of these changes are difficult to predict at this time, demand for the Company's TraitCheck Bt9 product has exceeded 400,000 tests shipped-to-date in the fourth quarter. Many factors led to this increased demand, including decisions by food processors to suspend operations until the volume of StarLinkTM corn has been accounted for or until supplies on-hand can be tested to ensure that StarLinkTM corn is not present. There is uncertainty as to whether and if so how long this need will persist and at what rate."

Commenting on the results of the quarter, Richard C. Birkmeyer, President and CEO of SDI stated, "While we are disappointed in the revenues for the quarter, we continue to be pleased with the results of our antibody business, representing 46% growth for the first nine months, and 16% this quarter. It reinforces the need for our company to shift from a product focus to a market focus, providing our customers with bundled products which complement each other. We are working diligently to restructure our water quality and agricultural groups to offer complementary products that allow end users to make informed decisions.

"We are disappointed with the results in the agricultural market for the third quarter. We made significant advances promoting the technology, therefore gaining acceptance by regulatory and industry leaders since the launch of the first GMO test kit for grain in July of 1999. Unfortunately, the lack of premiums for non-GMO grain resulted in the industry relying on paper certifications rather than testing. This has changed overnight with the recent events concerning StarLinkTM corn. From the outset, we were recognized as the leader in providing accurate, fast and inexpensive testing solutions for users. The foundation for this recognition lies in the relationship with our corporate partners and our market development efforts. With the general recognition of our capabilities by our customers who, from prior experience with SDI's GMO test kits were already familiar with the testing protocols and procedures, we were able to keep up with demand for the Bt9 test kit and provide more than 400,000 tests to the industry to date to identify and track StarLinkTM corn. However, to date, many future events could significantly affect demand and past shipments may not be indicative of future demand. We are attempting to expand the quality control systems that these companies are putting in place using our protocols for StarLinkTM corn test to include our other tests for Roundup Ready, Bt Cry1Ab, Liberty Link, and mycotoxin tests. As we look ahead to the rest of the fourth quarter of 2000, we believe revenues will be in line or ahead of a 25% increase over the third quarter of 2000, partly as a result of the StarLinkTM related sales."

In related news, the USDA Grain Inspection, Packers, and Stockyards Administration (GIPSA) recently evaluated SDI's TraitCheck Bt9 lateral flow strip test for detection of StarLinkTM Cry 9C in corn grain. The TraitCheck Bt9 was found to verify all test performance criteria as described by SDI and is the first test to be so evaluated by the USDA.

The TraitCheck Bt9 strip test is used in conjunction with SDI's GMO Check Bt9 ELISA to provide comprehensive testing for StarLinkTM corn from plants in the field, to trucks at elevators, railcars, barges and even ships containing corn for international trade. The superior sensitivity of the GMO Check Bt9 ELISA, 0.01% detection of StarLinkTM in composite grain samples, provides the critical information required by growers, distributors, and processors to assess levels of contamination with high statistical confidence.

Another SDI test, the GMO Check Bt1 ELISA for the quantitation of insect-protected Bt corn, has recently been the subject of a large international collaboration sponsored by the American Association of Cereal Chemists (AACC) involving 40 laboratories in 20 different countries. The results of these studies are currently in publication and will be presented at the upcoming meeting of the AACC during the first week of November. This is the second SDI test to undergo such a study. The performance of SDI's GMO Check Roundup Ready ELISA was previously validated in a 38 laboratory European study sponsored by the Joint Research Centre of the European Union.

SDI is a leading provider of biotechnology-based diagnostic tests for a broad range of agricultural, industrial, and water treatment applications. Through its antibody business, Strategic BioSolutions,

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Strategic Diagnostics also provides antibody and immunoreagent research and development services. SDI's test kits are produced in a variety of formats suitable for field and laboratory use, offering advantages of accuracy, cost-effectiveness, portability, and rapid response. Trait Check TM is a pending trademark for SDI.

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This news release contains forward-looking statements reflecting SDI's current expectation. When used in this press release, the words "anticipate", "enable", "estimate", "intend", "expect", "believe", "potential", "will" and similar expressions as they relate to SDI are intended to identify said forward-looking statements. Investors are cautioned that all forward-looking statements involve risks and uncertainties, which may cause actual results to differ from those anticipated by SDI at this time. Such risks and uncertainties include, without limitation, changes in demand for products, delays in product development, delays in market acceptance of new products, inability to obtain required government approvals, modifications of government regulations, modifications to development and sales relationships, the ability to achieve anticipated growth, competition, seasonality, and other factors more fully described in SDI's public filings with the U.S. Securities and Exchange Commission.

Company Contact: Arthur A. Koch, Jr. Chief Operating Officer (302) 456-6789

Investor Relations Contact: Lippert/Heilshorn & Associates, Inc. William A. Walkowiak, CFA Klea Theoharis (212) 838-3777

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STRATEGIC DIAGNOSTICS INC. ANNOUNCES AVAILABILITY OF RAPID FIELD TEST TO DETECT STARLINKTM CORN

NEWARK, DELAWARE, SEPTEMBER 26, 2000 - STRATEGIC DIAGNOSTICS INC. (NASDAQ: SDIX) - today announced the availability of two analytical test kits to detect the characteristic protein found in StarLinkTM corn. The first test is a quantitative analytical method in a microtiter plate format for laboratory use. The second test is an easy-to-use, rapid, strip-based method suitable for use in the field. These methods have been fully validated by SDI for use in detecting Cry9C protein in grain. These tests are designed to allow end-users to rapidly check for the presence or absence of StarLinkTM corn in grain samples. Validation for other uses is ongoing.

An individual strip test is designed to detect Cry9C protein in grain samples at a concentration of 0.25%. However, precise sensitivity is dependent on customer specifications and sampling procedures. The tests are capable of detecting concentrations of less than 0.1% using multiple samples. The quantitative microtiter plate test has sensitivity of less than 0.1% using a single sample. The test is available through SDI and interested persons should contact SDI's customer service groups at (302) 456-6789 and (800) 544-8881.

Richard C. Birkmeyer, President and CEO of Strategic Diagnostics, commented, "We are delighted to complete the licensing agreement with Aventis so that we can offer this new test, which is part of a portfolio of SDI products marketed under the trademarks Trait CheckTM and GMO Check TM by SDI and our marketing partner Agricultural Information Technologies through its newly formed business unit IdentityPreserved.com. We believe our tests are an important element in the StarLinkTM Stewardship Program and we are pleased to offer this rapid, cost-effective analytical solution with the full support of Aventis. We believe the events of last week have raised the awareness for the need for rapid analytical

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testing of genetically modified grain."

SDI is a leading provider of biotechnology-based diagnostic tests for a broad range of agricultural, industrial, and water treatment applications. Through its antibody business, Strategic BioSolutions, Strategic Diagnostics also provides antibody and immunoreagent research and development services. SDI's test kits are produced in a variety of formats suitable for field and laboratory use, offering advantages of accuracy, cost-effectiveness, portability, and rapid response. Trait Check TM is a pending trademark for SDI.

This news release contains forward-looking statements reflecting SDI's current expectation. When used in this press release, the words "anticipate", "estimate", "intend", "expect", "believe", "potential", "will" and similar expressions as they relate to SDI are intended to identify said forward-looking statements. Investors are cautioned that all forward-looking statements involve risks and uncertainties, which may cause actual results to differ from those anticipated by SDI at this time. Such risks and uncertainties include, without limitation, changes in demand for products, delays in product development, delays in market acceptance of new products, inability to obtain required government approvals, modifications of government regulations, modifications to development and sales relationships, the ability to achieve anticipated growth, competition, seasonality, and other factors more fully described in SDI's public filings with the U.S. Securities and Exchange Commission.

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STRATEGIC DIAGNOSTICS INC. ANNOUNCES LETTER OF INTENT TO PURCHASE AZUR ENVIRONMENTAL; LOWERS THIRD QUARTER ESTIMATES

NEWARK, DELAWARE - SEPTEMBER 26, 2000 - STRATEGIC DIAGNOSTICS INC. (NASDAQ: SDIX) - today announced that it has entered into a non-binding Letter of Intent to acquire AZUR Environmental. The purchase of AZUR Environmental, whose corporate headquarters are located in Carlsbad, California, is subject to due diligence and approval by both companies' Board of Directors, approval of the stockholders of AZUR and other conditions.

AZUR Environmental is a leading provider of innovative analytical systems for monitoring water quality throughout the world. Over 2,000 customers in over 59 countries have used their Microtox® products to provide reliable data regarding the toxicity of their water in a timely fashion. The reliability and speed of the technology is ideally suited for such applications as wastewater testing (municipal and industrial), surface and drinking water, soil and sediment testing, and monitoring biocide effectiveness. Their InSpectraTM product, for which they have exclusive rights in the U.S., provides a unique instrumental approach for the measurement of biological oxygen demand (BOD), chemical oxygen demand (COD), total organic carbon (TOC) and total suspended solids (TSS). These particular analytes are the most frequently measured analytes in water treatment facilities, of which there are approximately 27,000 in the U.S. alone. AZUR had sales of over \$3 million in fiscal year 2000, ended June 30.

Dr. Anthony Bulich, CEO of AZUR Environmental commented, "We believe the acquisition of AZUR by SDI will provide a unique and useful suite of products for use within the water quality industry. Further, we believe the combination of core technologies from the two





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AIT to Distribute TRAIT CHECK™ Crop Test

Third Quarter Results '99

New Mycotoxin Test Kits for the Grain and Feed Markets

JOSIC receives a non-exclusive laboratory certification for the test kits within Japan

Takara Shuzo to Distribute GMO Kits in Japan

Second Quarter Results '99

Soybean GMO Kit

AGREVO Agreement

Atlantic Antibody Acquisition

First Quarter Results '99

Monsanto Agreement

GMO Approval

GeneScan

HTI Acquisition

New York Gas

STRATEGIC DIAGNOSTICS SIGNIFICANTLY EXPANDS MARKET REACH FOR ITS TRAIT CHECK $^{\text{TM}}$ CROP TEST

Over One Thousand Field Sales Representatives Will Now Sell the Trait CheckTM Product Line Through Agricultural Information Technologies (AIT)

NEWARK, DELAWARE, NOVEMBER 29, 1999, STRATEGIC DIAGNOSTICS INC.

(NASDAQ NM: SDIX) - today announced that it has entered a distribution agreement with Agricultural Information Technologies (AIT) of Iroquois, South Dakota. SDI will work with AIT as a distribution agent for the Company's Trait Check TM test kits that are used for the detection of Genetically Modified Organisms in grain, leaf and seed. This agreement gives AIT exclusive rights for distribution and sale of the Roundup Ready TM Trait Check TM kits in the U.S. and Latin America.

AIT provides key components of an Identity Preserved System for input and output traits in seed, crop, grain and food products. The Postmark TM line of products assists businesses in effectively tracking agricultural materials. The Postmark brand products includes SIGNPOST TM, an on-site field marking system, SEEDTAG TM, a comprehensive database of seed traits for corn, soybeans, and cotton and CROPTOUCH TM, a process and material tracking system. AIT, in affiliation with its distribution





Year 2001 Press Releases Updated: Oct 25, 2001

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NEW

SDI Reports 49% Revenue Growth in 3rd Quarter & Ten-fold Increase in Net I

SDI Announces Collaboration with Molecular Circuitry, Inc. and McDonald's C

Strategic Diagnostics To Report Third Quarter Results on October 25

SDI Announces the Availability of New Test to Detect Monsanto's Roundup Ready® Corn

SDI Announces Closing of AZUR Environmental Acquisition and Sales of Microtox® Toxicity Testing System Utilities

SDI Reports Substantial Increases in Operating and Net Income for Second Quarter

SDI Ranked Among America's 100 Fastest-Growing Small Companies

SDI Announces Expansion Plans & Signing of Sales and Mktg Agreement with AZUR Environmental

SDI Announces Definitive Agreement to Aquire AZUR Environmental

SDI Announces 270% Increase in Adjusted Net Income for the First Quarter

USDA Verifies New GMO QuickCheck™ Bt9 Test Kit for StarLink™

Preliminary Results for the First Quarter Exceed the Company's Expectations

Record Year End and Fourth Quarter Results Reported

USDA Verification of TraitCheck BT9 Strip Test Received

Strategic Diagnostics Reports 49% Revenue Growth in Third Qua

Ten-fold Increase in Net Income

NEWARK, Del., Oct. 25, 2001 - Strategic Diagnostics Inc. (Nasdaq: SDIX) - a leading provider of antibody produtest kits for the food safety and water quality markets, today reported financial results for the third quarter ended Sept.

Revenue for the quarter increased 49% to \$8.5 million from \$5.7 million in the third quarter of 2000. Operating incom five-fold, to \$1,419,000 from \$281,000, with a corresponding ten-fold increase in net income, to \$896,000 from \$89,000 year. On a per share basis, fully diluted net income was \$0.05 versus \$0.01 for the same period last year. These results quarter of 2001 include approximately \$150,000 in expenses related to the previously announced consolidation of the



GMO Testing

By Bruce Floyd Contributing Editor

News about sickly butterflies and "tainted" taco shells garner headlines. Many of the country's overseas buyers now monitor importation of genetically modified organisms (GMOs). These are only some of the factors that have increased interest in methods to test for the presence of GMOs in foods and ingredients.

Step by step

GMO testing should begin with a series of questions:

- Why is the product being tested for GMOs?
- Is this a homogenous product?
- Is this a raw agricultural product, intermediate raw material or highly processed product?
- Is the product cooked or heat-treated?
- Is the testing to be done in-house or by an outside laboratory?

The reason behind testing is important. A company making a "GMO-free" claim must verify that the product is free of all GMOs on the market. This, in its most exacting form, would require "chain of custody" documentation to ensure identity preservation. Some firms offer "chain of custody" services and provide certificates from the farm to the final product. These services will take samples for analytical testing on those crops that have commercially available GMOs on the market at the various production stages.

GMO food crops at some development stage include certain types of corn (maize), soybeans, rapeseed (canola), potato, squash, papaya, chicory, melon, sugar beet, rice and tomatoes. Some varieties of these are not yet approved, but they are in field trials. Since this is an active industry, it is necessary to keep abreast of newly approved varieties or crops in this country and abroad.

Currently, it is impossible to test some highly processed foods for compliance since the markers used for detection are eliminated during processing. Some examples of these products are vegetable oil, sugar, corn syrup, pudding, margarine and soft drinks.

If a company exports a product to Europe, Japan or other countries that mandate GMO labeling of foods, the customer or host country may require a GMO analysis. Many countries have established minimum GMO levels below which mandatory labeling is not required. Also, if a country doesn't allow usage of all of the U.S.-approved varieties, specific testing for the unapproved variety may be required if the product contains detectable levels of those GMOs. In fact, the country may have a zero tolerance for an unapproved variety. Presently, the level of approved GMOs which trigger mandatory labeling is above 5% in Japan and above 1% in the European Union.

With the recent discovery in the human food supply of Starlink™, a genetically modified Bt corn variety (approved in the United States only for animal feed), the issue of how to check incoming raw materials for unexpected GMOs was suddenly added to the list of reasons for

testing.

Testing troubles

Certain non-analytical problems can affect GMO testing. No matter which method of analysis is used, sampling can be a problem. GMO contamination is a random event. Depending on its source, each grain kernel either is or is not GM. Depending on the method of transportation from farm to market, a lack of uniform distribution of one variety in another may occur.

Also, too small a sample will not be sensitive enough. When sampling grain, remember that it is a sampling of a discrete population. One corn kernel in 1,000 would be 0.1% of the total. Some sources recommend grain samples of approximately 1,500 to 3,000 grams to detect minute contamination levels. The sample size will depend upon what level is important and what one is looking for. It is very unlikely that the GMO material will be uniformly distributed throughout the lot.

Testing is only as good as the sample plan, and the sample plan is only as good as the knowledge of the population to be sampled. This would apply to any crop that is bulk-stored for later use, such as potatoes. Additionally, it is easier to sample processed foods if the finished product tends to be homogeneous. The USDA Grain Inspection, Packers and Stockyard Administration (GIPSA) has developed a Starlink sampling and testing guide that can be found at www.usda.gov/gipsa under GIPSA Directive 9181.1, Testing For Starlink™ Corn.

Additionally, the sampling device must be free of material before collecting the next sample. Just a few GM corn kernels left in the sampler will cause a positive result in the next sample. Excessive grain dust has been known to cause false positives, as well. Outside companies, such as Eurofins Scientific Inc., Memphis, TN, can set up a sampling program at each receiving site. They will determine how to take statistically valid samples from actual equipment observation and furnish trained personnel to take and process the samples for analysis.

Sample preparation introduces yet another problem. When grinding large samples, the sample preparation area requires environmental control. Several of the methods are very sensitive and dust drift can cause cross-contamination. Another avenue for cross-contamination introduction is the grinding and mixing equipment, which must be analytically clean at all times.

Testing types

At this time, there are two methods for the detection of GMOs: enzyme-linked immunosorbant assay (ELISA) and polymerase chain reaction (PCR). According to Michael Meyers, vice president, business development, Eurofins Scientific, "ELISAs detect or measure the amount of the protein of interest in a sample that may contain numerous other dissimilar proteins. ELISAs use one antibody to bind the specific protein, optionally a second antibody to amplify detection, and an antibody conjugated to an enzyme whose product produces a color that can be easily visualized and quantified based on comparison of a standard curve of the protein of interest."

ELISAs are available in two configurations: lateral-flow test strips which give qualitative results, and micro-titer test kits, which yield quantitative results. Strategic Diagnostics Inc., Newark, DE (www.sdix.com/food) makes kits developed for specific crops and events. ("Event" is the name given by the life sciences industry to a specific genetic manipulation.)

ELISA is faster and less expensive than DNA determination and can be set up in any laboratory. The kits are for sale to industry and also are used by third-party testing laboratories. The Trait Bt9 Lateral Flow Test Kit for Starlink was validated by GIPSA and is used to screen corn at elevators following GIPSA Directive 9181.1. By following the sampling procedures in the directive, it is possible to obtain a 99% confidence level of less than 0.15% Starlink for a given lot.

The lateral test kits, which are fast and relatively low-tech, give qualitative results that assure there is not more than a given amount of GM material in the sample. They will not guarantee no measurable amount of GM material is present; for that, the ore-sensitive micro-titer plate kits must be used. Depending on the event, they can detect levels down to 0.01%.

According to Donald Durandetta, Ph.D., marketing manager, Strategic Diagnostics Inc., ELISA is very event-specific. It gives relatively fast results and is very accurate when used correctly. But, the ELISA test presents two problems: it will not work on denatured protein, and the specific type of protein or variety must be known. It will not work on highly processed or cooked foods. Its recommended use is for raw or partially processed products.

Testing levels

There are several DNA or PCR testing levels. The life science industry uses a common promoter gene to fix the primer sequence or event in place. The most common one is cauliflower mosaic virus 35S, which is currently found in 32 GMOs. Many qualitative screens look for this promoter as an indicator that any event is present. It does not occur in tomatoes, so if you make products containing tomatoes, the 35S screen will not work for you. If the product does not contain tomatoes and there is a need for detecting the presence of GMOs for general labeling, the 35S screen will work for most purposes.

To detect non-approved GMOs for any reason, more specific tests will have to be run and at a lower detection level. In this case, the analyst will look for the specific primer sequence that is supposed to be present. However, the actual primer sequences are patented and unavailable to the public. Testing labs without access to the actual primer sequence must approximate the primer in order to develop specific quantitative procedures to detect and measure it.

According to USDA/GIPSA's Steve Tanner, director of analytical services, Kansas City, MO, USDA/ GIPSA has obtained samples of all the primer sequences used in grain crops under confidentiality agreements made with all of the life science companies. It will send out samples of corn and soybean varieties containing different levels of GMOs to all DNA testing laboratories in the United States that desire method verification. The lab results will then be compared to the results GIPSA obtains using the actual primer sequences. This will be the first validation of GMO DNA testing done by a governmental agency, anywhere. Until then, companies must depend on a laboratory's reputation as well as evaluate its methods. It would be helpful if the EPA and/or FDA would require the life sciences industry to submit the primer sequence for analytical development at the same time they submit application for approval to commercialize a new Bt variety.

Several PCR methods exist in the marketplace. Two of these are proprietary and are used by their developers to analyze submitted samples. One of these companies, Genetic ID, Fairfield, IA (www.geneticid.com), has extensive experience with DNA testing and offers a good methods and practices explanation on its website. The company offers quantitative analysis of all GMOs as well as less expensive 35S qualitative screening procedures. Another lab that uses PCR for DNA enumeration is Eurofins Scientific Inc. It offers both DNA along with ELISA for GMO analysis depending on the product and accuracy level needed.

If one is thinking about purchasing a DNA system for in-house testing, DuPont Qualicon, Wilmington, DE (www.qualicon.com) offers the BAX® kit for qualitative screening of GMO (35S) and quantitative screening for soy. According to Scott Fritschel, Ph.D., product manager, this high-tech BAX kit offers several advantages over other PCR test methods: tabletted regents eliminate the need for preparation and repeated pipettings of reagents; and the system uses closed-tube detection, which eliminates the possibility of PCR cross contamination and increases detection sensitivity. Because the test system is high-tech, it is not recommended for everyone.

Most companies will send samples to a third-party lab for analysis. Since the PCR method amplifies the DNA fraction a billion times, minute levels of contamination can play havoc with accuracy. Because DNA methods are expensive, anyone should scrutinize lab procedures before sending in samples. The Genetic ID website lists 12 questions to ask before hiring a DNA testing lab. While the questions are somewhat self-serving, they do address important issues since public verification methods are lacking.

The method choice depends on why the information is needed. As a general rule of thumb, the more demanding the customer, the more expensive the cost of providing the information. Also, the more exact the procedure, the more expensive and time consuming it will be. Finally, a more highly processed product will have less analysis options. Often, GMO certification cost may be much higher than anticipated.

Bruce Floyd established Process Systems Consulting, lowa City, IA, after working more than 30 years in the food processing industry. He has had extensive experience in sanitation, quality control, regulatory relations, and product and process development (both domestic and international), and specializes in integrating ingredient and manufacturing specifications into total process systems. A graduate of Georgia State University, he has successfully completed all areas of the Better Process Control School at the University of Minnesota, and has been qualified by the International HACCP Alliance as an instructor. He can be reached via e-mail at bfloyd7192@aol.com.

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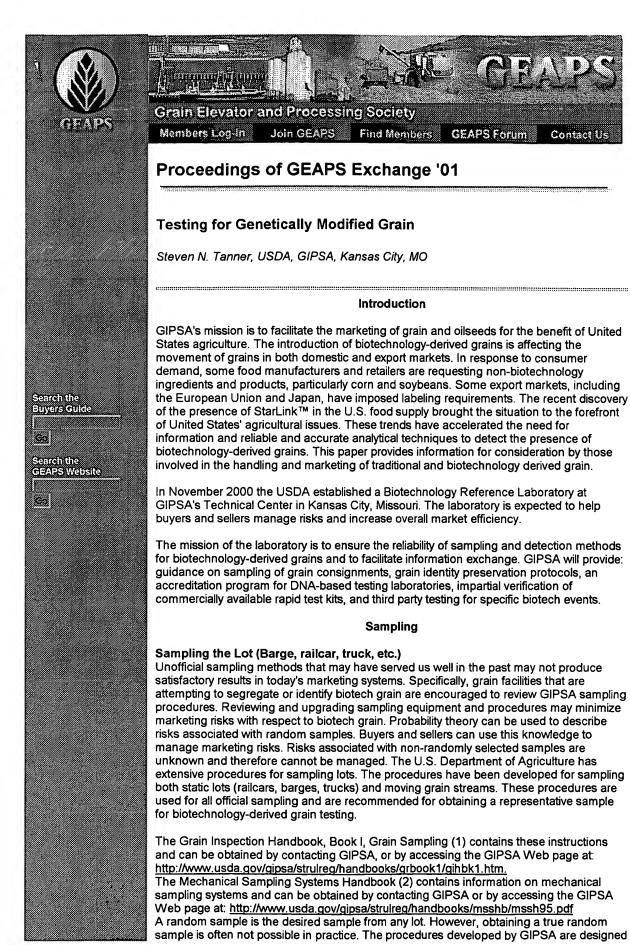
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to provide an approximation of a random sample. GIPSA handbooks refer to these samples as representative samples. http://www.usda.gov/gipsa/strulreg/handbooks/msshb/mssh95.pdf

A sample is taken from a static lot by using a hand probe and the appropriate probe pattern. The probe pattern provides designated locations on the surface of a grain lot from which a grain sample is obtained with a probe. Each probe sample is commingled to obtain a representative sample for the lot. Probe patterns have been developed for all sizes and shapes of containers. The probe should be of sufficient length to reach the bottom of the container.

A representative sample can also be taken from a moving grain stream. A mechanical device called a diverter-type mechanical sampler is permanently installed in a grain stream, often near the discharge point of vertical bucket elevators. This is the preferred sampling method for estimating any parameter of a grain lot. An oblong cup-like apparatus periodically traverses the grain stream, collecting a grain sample each time. This sample may be further reduced with an automatic divider and finally commingled with other such samples from the lot. The commingled sample is the representative sample from the lot.

The primary sample from a lot is designed to be larger than required for testing. GIPSA sampling methods yield samples that are larger than two kilograms. To obtain a test portion, the Boerner divider is used to reduce the primary sample down to the appropriate size for the various tests.

A properly obtained sample is critical in the testing of any grain lot for any attribute. Without a good sample, the value of all testing on the sample is diminished.

Sample Acceptance Plans

Measuring a sample from a lot is a cost-effective means of obtaining information on a lot. Unfortunately, samples will vary in the amount of the constituent of interest. Also, the parameter being measured and the analytical method may introduce variation in measurements. Probability theory can be used to describe the variation (3). The parameter being measured, the sample size, and the number of samples tested influence the measurement variability. By choosing an appropriate sample size and number of samples tested, buyers and sellers can manage the risks associated with sampling variability.

In grain inspection, constituents are usually reported as a percent of the total weight. A logical extension to biotechnology-derived grain is to report the percent of the lot that is biotechnology-derived kernels. This implies that biotechnology-derived kernels can be identified. The technology for measuring biotechnology-derived grain typically measures DNA or expressed proteins. Some unresolved issues arise in trying to convert the amount of DNA or expressed protein to percent biotechnology-derived kernels. At this time, qualitative testing is believed to be the most reliable test. The guidance in sample plans has focused on qualitative testing.

Single Sample - Qualitative Testing

The model of a grain sample is a collection of kernels from a grain lot. One objective of testing may be to estimate the amount of biotechnology-derived kernels in the lot. Qualitative testing will not provide an estimate of the amount of biotechnology-derived kernels in the lot. Qualitative testing produces a positive result if one or more biotechnology-derived kernels are in the sample and produces a negative result if no biotechnology-derived kernels are in the sample. A positive result may mean that one biotechnology-derived kernel was present in the sample or that all kernels in the sample were biotechnology-derived.

Figure 1 gives plots of probabilities of negative results for selected sample sizes. The probability of a negative result decreases as the percent biotechnology-derived grain in the lot increases. Larger samples will cause the probability of a negative result to decline much faster. A sample size can be chosen to limit the chances of accepting an unacceptably high concentration of biotechnology-derived grain in the sample.

Significant error rates with the analytical method can influence the probability of observing a negative result. A significant false positive error rate would mean that some samples with no biotechnology-derived kernels would test positive. A significant false negative error rate would mean that some samples containing biotechnology-derived kernels would test negative. The curves in Figure 3 would be noticeably altered if significant positive or negative error rates exist with the analytical method. Fortunately, in the limited testing of



biotech test kits, the false positive and negative error rates appear to be small. As long as this trend continues with other biotech test kits, false positive and negative error rates can be ignored in evaluating test plans.

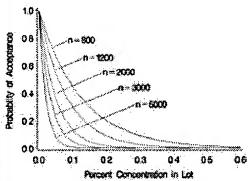


Figure 1. Probabilities of negative results

from a qualitative test with samples of 800, 1200, 2000, 3000, and 5000 kernels.

Multiple Samples - Qualitative Testing

A single large sample serves the buyer's interests well. However, some buyers may be willing to accept some low concentrations while unwilling to accept high concentrations. Sellers of lots with low concentrations would like to have high probabilities of these lots being accepted. Decreasing the sample size will increase the chances of a negative result on low concentrations. Unfortunately, decreasing the sample size increases the chance of a negative result with higher concentrations. A single qualitative test may not serve the interests of both the buyer and the seller. An alternative is to implement a multiple sample plan.

Multiple sample plans specify that a certain number of independent samples will be selected from the lot and each sample is tested. The buyer will accept the lot if certain combinations of positive and negative test results are obtained. For example, the sample plan may specify that five samples of 100 kernels will be selected from a lot. If no more than three positives are obtained on the five tests, then the lot is acceptable.

The components of a multiple sample plan are the number of samples, the size of each sample, and the maximum number of samples testing positive. Changing any one or more of these parameters affects the probability of acceptance. Buyers and sellers can choose a plan based on the risks they are willing to assume, and on the cost of conducting the tests.

With the example of five samples of 100 kernels, the maximum number of positives specified in the plan could be one, two, three, or four. Figure 2 gives the probabilities of accepting lots with these four plans. Increasing the maximum number of acceptable positives will result in higher concentrations being accepted.

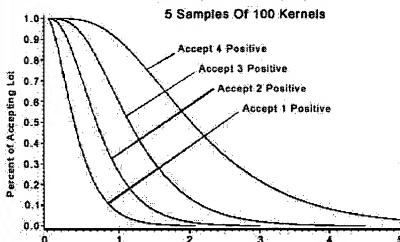
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Figure 2.



Multiple Sample Qualitative Testing

Probability Of Accepting Lots



Percent Concentration in Lot

Probabilities of accepting four multiple sample plans.

Grain Identity Preservation Protocols

Protocols to improve confidence that grain shipments meet certain contract specifications are likely to become more widely used. GIPSA has cooperated in the implementation of one such protocol to satisfy Japanese importers of food corn that StarLink™ corn is not present in export shipments. Under this protocol, the official inspection system provides official testing of domestic shipments (barge or rail) expected to be exported to Japan. Containers are sampled via official sampling procedures and at least three sub-samples of 400 kernels each are tested by rapid test methods. The testing protocol has the goal of rejecting corn with one or more kernels of StarLink™ in 1200 kernels for export to Japan. If any sub-sample tests positive, that barge or railcar is excluded from the identity protocol. All units that test negative are physically sealed and included in the identity protocol. At export port locations official inspection personnel monitor the export elevator's processes for avoiding inadvertent commingling of grain and the inbound and outbound transfer of grain included in the protocol. The Protocol for Food Corn Exported to Japan may be found on the GIPSA Web page at: http://www.usda.gov/gipsa/biotech/starlink/protocol.htm The Guidelines for Implementing the Protocol for Food Corn [Yellow] Exported to Japan may be found on the GIPSA Web page at: http://www.usda.gov/gipsa/biotech/starlink/guidelines.htm

The grain industry should explore certification programs and standardized identity preservation protocols. This need should become more apparent as value-added, end-use attributes created through biotechnology are introduced into the market. In the case of grains such as wheat, where no biotech is currently in commercial production, there is great potential to avoid some of the problems the markets experienced during the first wave of biotech grain introduction.

DNA-Based Testing and Laboratory Accreditation Programs

A promising DNA-based testing technology currently available for identifying grains with biotechnology-derived traits is Polymerase Chain Reaction (PCR). While the technology shows promise, limited technical information or performance verification by an unbiased third party has been conducted. GIPSA maintains a state of the art PCR testing laboratory in Kansas City. To promote confidence in testing methodology and commercially available testing services, the laboratory will evaluate and maintain DNA-based testing technology and carry out a DNA-Based Testing Laboratory Accreditation Program (4).

PCR is a detection technique which "looks" for specific DNA base sequences, or foreign genes, that have been inserted into the organism's DNA. PCR uses primers to target specific base sequences unique to the foreign DNA and then amplifies these sequences, often one million-fold, through a series of processes. PCR then uses gel electrophoresis to detect the presence of the modified DNA. If the primers contact the target gene, specific



bands will be present on the electrophoretic plate; products that do not contain the target gene will not have these bands. Positive and negative controls are analyzed with each set of unknowns for confirmation purposes.

PCR offers the following advantages:

PCR is very sensitive

PCR is specific for the target DNA base sequence (genetic modification)

PCR can provide semi-quantitative results

PCR may be suitable for processed food, dependent on the process and the stability of the DNA

PCR has some distinct disadvantages:

PCR typically takes two to three days to complete the analysis

PCR requires relatively expensive equipment and a laboratory environment

PCR requires expertise to conduct the test and evaluate the results

PCR is generally specific for a particular genetic modification; i.e., it would be difficult and expensive to analyze for multiple genetic modifications in a particular grain or product Cost per sample varies from about \$200 - \$500

For now, time and cost considerations limit large-scale utilization of PCR testing in day-to-day operations. Private testing laboratories are in the best position to meet the market's need for PCR testing services. Applicants for GIPSA's accreditation program must be functioning laboratories with trained personnel and requisite equipment and instrumentation. To receive accreditation, laboratories must demonstrate capability to accurately analyze for the presence of biotech grains. More than 25 laboratories have expressed interest in the program.

Verification of Commercially Available Rapid Test Kits

To effectively market biotech and non-biotech crops, the grain and food industries must have access to reliable detection methods to measure the value of improved quality attributes and to distinguish biotech from non-biotech crops. With reliable testing methods, all participants in the production and marketing system, from farm to end-user, can receive accurate information.

GIPSA will evaluate rapid tests that are commercially available in U.S. to test for the presence or absence of biotech products to facilitate the marketing of U.S. grain products, both domestically and internationally. The program is called Performance Verification of Rapid Tests for the Detection of Biotech Events (5). Rapid tests utilizing Enzyme-Linked Immunosorbent Assay (ELISA) technology have been developed specifically to detect the presence of biotech grain. GIPSA offers performance verification of rapid tests in two formats:

Microtiter Well ELISA Technology: Tests designed to detect the presence of biotech grains through the detection of a specific protein produced in the biotech grain. These tests provide quantitative and/or qualitative results using antibodies incorporated into microtiter wells and enzymatic, colorimetric reagents for detection.

Lateral Flow Strip ELISA Technology: Tests designed to detect the presence of biotech grains through the detection of a specific protein produced in the biotech grain. These tests generally provide qualitative results using antibodies and color reagents incorporated into a lateral flow strip.

ELISAs are commonly used in a variety of assays (mycotoxins, bacteria, pregnancy tests, etc.) and have been used in GIPSA's Official Inspection System for many years to provide relatively inexpensive, easy to operate, and rapid analyses for mycotoxins. ELISAs take many forms, but generally, an animal is inoculated with a target compound, the animal produces antibodies to that compound, and then this biochemical relationship is used as a mechanism for isolating and detecting the target compound.

The ELISA approach is fundamentally different from the PCR approach. The PCR technique detects a particular DNA-base sequence; the ELISA technique generally detects a specific amino acid sequence, or protein, produced as a result of the genetic modification. Using glyphosate-tolerant (RoundUpÒ Ready) soybeans as an example, PCR detects the DNA sequences that have been inserted into the soybean DNA, but ELISA detects the specific protein that is expressed as a result of the genetic modification. Clearly, this protein must be uniquely associated with the genetic modification and be sufficiently

different from other proteins to avoid a high incidence of false positives.

ELISAs offer the following advantages:

ELISAs are generally rapid; the ELISA test kit that has been developed to test for StarLink™ can be completed in 10 minutes

ELISAs are generally sensitive (this will be dependent on the degree of expression and sensitivity of the antibody)

ELISAs do not require expensive equipment

Non-technical people can be trained to conduct the test

ELISAs offer the following disadvantages:

ELISA test kits are not available for all biotech grains grown commerciallyin the U.S. at this time

As with PCR, ELISA test kits are usually specific for a particular genetic modification, but it is possible that test kits capable of detecting multiple genetic modifications could be developed

ELISA tests are dependent on the expression of the foreign protein by the plant, which can be influenced by environmental factors

ELISA tests are often not suitable for the testing of processed foods, as the expressed protein may be removed, altered, or destroyed during processing

Performance is verified based on data submitted by the manufacturer and on an in-house verification conducted by GIPSA staff. Rapid tests that successfully meet GIPSA standards of performance will be awarded a Certificate of Performance. The certificate will automatically expire three (3) years from the issue date. The laboratory will meet the market's need for impartial, professional verification of these technologies. Grain markets rely on GIPSA as an unbiased entity to supply this important function in facilitating the marketing of grain.

GIPSA's experience with and evaluation of biotech testing technologies have revealed a few potential problems. For example, when using the Trait4Bt9 Lateral Flow Test Kits:

If StarLink™ is blended into the corn lot at a low percentage, then two independent tests could get different results due to random variation among samples.

The test strip result must be recorded at the specified development time of 10 minutes.

With one particular strip, false positive results may occur when no buffer is added to the test solution.

False positive results may occur when the strip is allowed to stay in the test solution over the allotted time.

As of January 9, 2001, GIPSA has verified the performance and issued certificates for two commercially available test kits for Cry9C protein.

Official Testing for Specific Biotech Events

GIPSA and its official inspection agencies offer official testing for StarLink™ corn. The service is not available for processed corn products. The service is described in Directive 9181.1 and became available on November 15, 2000 (6). Currently, GIPSA provides a qualitative service (yes/no) using the Trait4TM Bt9 Corn Grain Test Kit (Lateral Flow Strip) supplied by Strategic Diagnostics Incorporated.1/ and the QuickStixTM Cry9C Test Kit supplied by EnviroLogix, Inc. The test kits are capable of screening, at a detection level of 0.125% (1 kernel in 800), for the Cry9C protein.

The test protocol does not determine the exact percent of StarLink™ kernels. It determines the probability that a lot contains greater or less than a specified threshold concentration. To provide our customers with a high level of confidence in test results, GIPSA has adopted procedures that analyze triplicate portions containing 800 kernels each, for which negative test results provide 99 percent confidence that a lot contains no more than 0.19 percent of StarLink™ corn.

Summary

The use of biotechnology to alter or move genetic material into a plant to express desired traits will accelerate. The results will produce a new generation of disease and pest



resistant grains and value-enhanced traits designed to meet specific market needs.

At the same time, a rise in consumer preference for choice between biotech and non-biotech products is resulting in niche markets and the need for testing and segregation. The grain industry needs to understand the sampling, testing, and segregation issues and options involved in this new marketing environment. GIPSA will facilitate grain marketing and assist the grain industry by providing guidance on sampling of grain consignments, grain identity preservation protocols, an accreditation program for DNA-based testing laboratories, impartial verification of commercially available rapid test kits, and third party testing for specific biotech events.

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Current Protocols in Field Analytical Chemistry HIGHLIGHTS

UNIT 1C.4 Field Screening of VOCs in Ground Water Using the Hydrosparge VOC Sensor (William M. Davis, John S. Furey, and Beth Porter, U.S. Army Corps of Engineers, Vicksburg, Ms.). The Hydrosparge (HS) volatile organic compound (VOC) sensor has been developed for rapid characterization of ground water using direct-push techniques. The sensor consists of a direct-push ground-water sampling well (e.g., PowerPunch), an in situ sparge module, and a direct-sampling ion trap mass spectrometer (DSITMS). The equipment is designed to be used with a standard geophysical cone penetrometer truck (CPT) capable of advancing direct-push sampling tools. The DSITMS technique described in this unit is capable of meeting the precision and accuracy performance criteria defined in EPA Method 624. The time required for the HS measurement depends on the depth of penetration; in general 1 hr is need for penetration depths <25 feet and ~2 hr for depths down to 150 feet. Once water is obtained in the sampling well, the DSITMS measurement takes ~5 min.

UNIT 1B.2 Determination of VOCs in Fire and Chemical Accidents by Mobile GC/MS (Gerhard Matz, Technische Universitaet Hamburg-Harburg, Hamburg, Germany). On-site identification of hazardous compounds in fire and chemical accidents is performed with a new mobile GC/MS system. The instrumentation can be installed in a transportable container or a helicopter, and skilled firefighters--rather than analytical chemists--can operate the system. Four protocols in this unit address the determination of VOCs by GC/MS. The first is for determination of VOCs in air by preconcentration on sorbent materials such a Tenax. Two protocols describe the determination of VOCs in water used for extinguishing a fire--the spray-and-trap procedure is recommended for heavily contaminated samples because foaming is prevented, while the purge-and-trap procedure is recommended for nonfoaming samples. The fourth method is the determination of VOCs in soils by a headspace GC/MS method.

UNIT 1G.1 Determination of VOCs Using the Draeger Chip Measuring System (Wolfgang Baether, Drager Sicherheitstechnik GmbH, Lubeck, Germany). The Draeger chip measuring system for measuring toxic chemicals in air makes use of colorimetric chemical determination reactions (CCDR). The chip measuring system (CMS) consists of analyte-specific calibrated chips and a combined sampling and evaluation device, the analyzer. After a suitable chip is inserted into the analyzer, the measurement is started by moving a switch, and takes 60 sec to 10 min (depending on the analyte concentration); the result, in parts per million of analyte, is displayed on the analyzer. This technique can be used for the determination of ammonia, benzene, carbon monoxide and carbon dioxide, chlorine, hydrochloric acid, hydrocyanic acid, hydrogen sulfide, nitrogen dioxide, nitrous fumes, perchloroethylene, petroleum hydrocarbons, sulfur dioxide, toluene, vinyl chloride, and xylene.

UNIT 2C.2 Determination of PCBs in Soil and Water by ELISA (Donald W. Durandetta, Strategic Diagnostics, Inc., Newark, Del.). This unit describes the extraction of of PCBs from soil samples using methanol-based commercial soil extraction kits and their determination by the immunological enzyme-linked immunosorbent assay (ELISA). ELISAs are attractive in environmental analysis because of the high sensitivity and high degree of selectivity of antibody binding, the relatively low cost compared to GC methods, the high throughput (batches of 12 to 25 samples can easily be precessed in 1 hr), and the potential for use in the field. Three different test kits, including the EnviroGard, EnSys, and RaPID Assay, are described in this unit.

11/8/01 11:01 AM

UNIT 2B.1 Determination of Selected Pesticides in Water by SPME and GC/MS (Tadeusz Gorecki and Janusz Pawliszyn, University of Waterloo, Waterloo, Ontario, Canada). Solid-phase microextraction (SPME) is a solventless extraction technique that uses a small fused-silica fiber coated with a polymeric stationary phase such a poly(dimethylsiloxane), or PDMS. The analytes are absorbed or adsorbed by the stationary phase (depending on the type of coating) until the system reaches equilibrium. The amount of analyte extracted by the coating at equilibrium is determined by the distribution ratio of the analyte between the sample and the coating. This unit describes a procedure for the determination of 12 pesticides in water at part-per-billion levels. The turnaround time per sample is ~50 min (45 min for extraction, 5 min desorption), which is similar to GC/MS analysis. On average 12 samples can be analyzed in 8 hr.

UNIT 2D.3 Determination of PCP in Soil Using a Colorimetric Field Method (Joan McLean, Envirol, North Logan, Utah). This unit describes a method for the determination of pentachlorophenol (PCP), which uses a photochemically induced oxidation-reduction reaction between PCP and a reagent that becomes colored as a result of the reaction. The color that develops is proportional to the concentration of PCP in the sample. The method detection limit is 1.5 mg/kg with a dynamic range of up to 100 mg/kg. Because this is an oxidation-reduction reaction between halogenated compounds and the reagent, many halogenated compounds will give a response; to eliminate interferences from other compounds, an acid-base cleanup is included in the procedure. This procedure gives results comparable to those obtained with EPA Method 8040.

UNIT 2E.2 Fiber-Optic Sensor for the Determination of Irgarol-1051 in Seawater (M.A. Gonzalez-Martinez, R. Puchades, and A. Maquieira, Universidad Politecnica de Valencia, Valencia, Spain). The development of a fiber-optic immunosensor for the s-triazine antifouling agent Irgarol-1051 and its application to the continuous analysis of this compound in seawater samples are described. The device uses a special cell containing a protein A/G immunocomplex-capture sorbent and spectrophotometric detection. The sensor can carry out an on-line analysis in 30 min in a totally automated fashion with a limit of detection of 14 ng/L in seawater.

UNIT 3B.3 Determination of Metals in Soil by XRF Spectrometry via Cone Penetrometry (SCAPS) (W. T. Elam, Naval Research Laboratory, Washington, DC). This unit describes the use of the SCAPS XRF sensor developed at the Naval Research Laboratory. Unlike other field-portable XRF instruments, this sensor uses an electrically excited X-ray tube as an X-ray source, and it is protected by a rugged yet X-ray-transparent window. In conjunction with the cone penetrometer truck, the SCAPS XRF sensor provides XRF spectra of target analytes in situ at depths down to >50 m.

UNIT 5A.1 Determination of Nitrate in Aqueous Matrices Using Nitrate Reductase (Ellen R. Campbell and Wilbur H. Campbell, The Nitrate Elimination Co., Lake Linden, Mich.). Nitrate is a common contaminant in ground water and surface waters worldwide. Current detection methods include ion chromatography, use of ion-selective electrodes, and wet chemical techniques; they are expensive, require highly trained personnel, suffer from contaminant interferences, and use chemicals that are environmentally harmful. This unit describes a colorimetric method for nitrate determination using the enzyme nitrate reductase, which catalyzes the reduction of nitrate to nitrite. After the enzymatic reaction is complete, nitrite is reacted with two reagents (diazo chemistry), and the color (a measure of the amount of nitrate in the original sample) is quantitated by measuring the absorbance at 540 nm. The assay can be performed in either test-tube or 96-well-microtiter-plate formats.

UNIT 2F.1 Fully Automated On-Line Monitoring of Pesticides in River Water Using HPLC with Diode-Array Detection (S. Lacorte and D. Barcelo, CID-CSIC, Barcelona, Spain). A modified SAMOS (System for Automated Monitoring of Organic Pollutants in Surface Water) is used to analyze 8 water samples per day in unattended operation for at least 5 days. The SAMOS consists of a preconcentration unit for extraction of compounds using solid-phase extraction and an HPLC system with diode-array detection. The modifications done to a commercial SAMOS, which described in this unit, include (1) addition of a sampling module that consists of a pump and four refrigerated flasks and (2) incorporation a novel filtering device to prevent clogging of the HPLC system. Calibration data and method repeatability and reproducibility data are presented for 8 pesticides.

UNIT 3C.2 Determination of Mercury in Soils by ELISA (B. Holmquist, C. Schweitzer, and M. Riddell, BioNebraska, Inc., Lincoln, Nebraska). This unit describes an immunological screening procedure for the

determination of mercury in soils at 0.5 mg/kg. Soil samples are extracted with 2:1:1 hydrochloric acid/nitric acid/water for 10 min; the extract is then buffered and incubated with BSA-glutathione. Mercury ions in the sample bind to the sulfhydryl groups of the glutathione and are subsequently detected with another antibody specific for mercury. Although the total analysis time is 35 min per sample, large batches of samples can be processed in parallel, allowing high throughput. Although, unlike the cold-vapor atomic absorption spectrophotometry currently used in laboratories, this immunological procedure is not fully quantitative, it uses a relatively large sample size (e.g., 5 g), which makes it more representative of the soil being monitored.

UNIT 3D.3 Field Determination of Mercury in Solids and Solutions by Thermal Decomposition, Amalgamation, and Atomic Absorption Spectrometry (H.M. Boylan and H.M. Skip Kingston, Duquesne University, Pittsburgh). A field method using thermal decomposition, amalgamation, and atomic absorption spectrometry with a typical working range of 0.05 to 600 ng mercury (sample size are 0.01 to 0.5 g for solids and 10 to 500 mL for aqueous samples) is presented in this unit. The analysis time is 5 min per sample. This method allows the determination of total mercury, organic, inorganic, and elemental mercury in solid and liquid matrices with a relative standard deviation <10%.

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AGNET JUNE 20, 2000 -- III

Proven Seed: GMO confusion has little impact on canola seed market
Accidentally planted on `GM-free' si te
GM crop testing grows amid controversy
Researchers aim to take cone out of coniferous: tree project latest in
genetic modification
Brazil blocks more Argentine corn as GM-suspect
Brazil may grow GM grain if price right
GM sales to be checked against diseases
Modified food regulator gets sharp teeth
When the label fits
Early-warning system to detect spread of asiatic citrus canker
Bug threatens canola;
Milkweed order threatens monarchs: homeowners told to kill `noxious weeds'

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archived at:

http://www.plant.uoguelph.ca/safefood/archives/agnet-archives.htm

PROVEN SEED: GMO CONFUSION HAS LITTLE IMPACT ON CANOLA SEED MARKET June 20, 2000

Proven Seed press release

WINNIPEG, MANITOBA Despite the debate that has dominated newspaper articles, broadcast commentaries and coffee shop conversations this winter, the controversy about genetically modified organisms turned out to have little effect on growers canola variety selections.

"There was actually minimal impact on the market," says Bruce Harrison, canola product manager for Proven Seed. "Although timing of sales was delayed in some seed segments, by end of season there was very little shift in the market versus 1999. Conventional canola varieties and canola with the Roundup Ready ® trait held share while there was modest growth in the SMART ® canola segment," he adds.

Harrison attributes the growth in the SMART segment to a shift in grower-buying decisions. "The herbicide tolerant market is maturing and we find growers are getting back to what's important. Yield and agronomic performance are the drivers - that's why Pioneer ® brand 46A76 led the market in early season sales."

46A76 was introduced commercially this year, but the variety was widely

tested in more than 50 farmer-run field-scale trials across western Canada last summer, with impressive yields and field performance. "I like the height of 46A76. It's not too tall, so it's easy to swath. It

"I like the height of 46A76. It's not too tall, so it's easy to swath. It cuts and combines like a dream," says Dale Dilworth of Rathwell, MB who tested the variety in his Local Performance Check trial in 1999 and liked the results so well that he grew it again in 2000. "With 46A76 there is no problem with lodging. A few years ago, we had canola that was so tall it got all twisted up and was tough to cut. Not this stuff."

In addition to excellent lodging tolerance and blackleg resistance, 46A76 also showed improved tolerance to sclerotinia in small plot and Local Performance Check trials. 46A76 is tolerant to ODYSSEY ® and PURSUIT ® herbicides. Proven Seed is the exclusive marketer of canola varieties with the SMART trait.

With the large number of varieties introduced each year, Harrison recommends field tours as the first step in the variety decision process. "Growers should continue to evaluate canola varieties based on features that are most important to their farms. Don't get distracted by controversy or glitz," says Harrison.

Those interested in seeing how 46A76 and other varieties are performing in their area can visit any one of more than 100 Local Performance Check sites this summer. A complete list of sites and upcoming tours is available by calling Proven Seed at 1-800-565-7333, or through their web-site at www.provenseed.com.

ACCIDENTALLY PLANTED ON `GM-FREE' SI TE June 20, 2000

PA News

Joe Quinn, Scottish Political Editor

UK rural affairs minister Ross Finnie was cited as saying that a crop of supposedly GM-free oil seed rape being used in a scientific trial in Scotland was planted instead with contaminated seed and that a "control" plot of oil seed rape, supposedly GM-free, that was being grown at a farm at Daviot, Aberdeenshire, alongside a GM crop, had been planted with contaminated material from affected Advanta batches.

But he said there was no risk to public health or the environment, the discovery would not affect the scientific validity of the trial, and there was no need to halt it.

When the research is completed both the control crop and the trial crop will be destroyed and will neither be marketed nor enter the food chain, he added.

GM CROP TESTING GROWS AMID CONTROVERSY
June 2000
Today's Chemist at Work
Volume 9, No.6, 32, 33, 37.
http://pubs.acs.org/hotartcl/tcaw/00/jun/stave.html
James W. Stave and Donald Durandetta

After a long introduction about the current state of ag biotech, this report says that an alternative approach for determining whether a food contains ingredients derived from agbiotech crops is to check a representative sample for novel DNA or its resulting protein. The quantity of agbiotech crop in the food is then determined by extrapolation from the sample's results. An inherent difficulty with this approach is that the

analytical techniques measure protein or DNA, but the laws mandate labeling based on the percentage of genetically modified organisms (GMO) present in an ingredient. The definition of %GMO is crucial to determining concentrations and is operationally defined as the percentage of positive beans, kernels, seeds, or other discrete units present in a pool of non-GMO units. For example, 1 GMO soybean mixed with 99 non-GMO beans represents a 1% GMO. Europe has currently established a 1% GMO threshold with respect to food labeling, and Japan has established a

5% threshold. To support labeling, a measurement technique must be able to determine whether the concentration of GMO in the sample is above or below the mandated threshold concentration with some specified level of confidence, accuracy, and precision. Techniques are available for detecting both proteins and nucleic acids, and their relative merits are the subject of considerable scientific debate (5, 6). It is possible to detect the novel DNA sequences present in agbiotech crops and ingredients using techniques such as the polymerase chain reaction (PCR). A PCR method for detecting the CP4 EPSPS gene, which confers resistance to the herbicide Roundup, was evaluated in a European Ring Study organized by the Joint Research Centre (JRC) of the European Union (7). The study findings demonstrated that the PCR method could detect the CP4 EPSPS gene, but only qualitatively. Thus, the method was not suitable for

use in determining whether a sample contained GMO above or below a mandated threshold concentration.

Novel proteins can be detected in agbiotech crops and processed food fractions using immunoassays. Like PCR, an enzyme-linked immunosorbent assay (ELISA) that detects the CP4 EPSPS protein was also evaluated in a European Ring Study by the JRC (8). The test protocol was designed to determine themethod's capability of distinguishing whether a sample contained GMO above or below an arbitrary threshold of 2%. The findings demonstrated that the samples identified as negative by the test contained less than 2% GMO, and samples that scored positive contained at least 0.85% GMO with a confidence of 99%. The

within-laboratory repeatability was $\pm 7\%$, and the reproducibility between laboratories was $\pm 10\%$. Although the test was designed specifically to determine whether a sample was above or below a specified threshold, the data clearly demonstrated that the test could be used to determine GMO concentration quantitatively. Realistic Tests The utility of any testing method is ultimately limited by the nature of the pecific application.

Because of technical as well as practical considerations, food processors have not

implemented large-scale testing programs to determine GMO concentrations in support of labeling. Instead, they have pushed the burden back on their raw material su ppliers, the grain distribution system. Without question, the most critical point of monitoring in the grain distribution system is at the initial point of sale, that is, when the producer sells to the local elevator. As

larger pools of grain are created, it becomes increasingly difficult and costly to acquire and analyze enough samples to get an accurate representation of the distribution of grain in a container. The majority of grain is harvested during a frenzied period of time, typically two weeks, in which trucks are standing in line at elevators and moving through the system at a rate of about one every five minutes. Grain as a commodity cannot support much in the way of additional

costs associated with testing. Under these conditions, it is critical to test grain immediately, on-site, at very low cost per sample, and the assay must be simple to use. Quantitative PCR is a highly complex procedure, requires expensive instrumentation and laboratory facilities, costs anywhere

from \$400 to \$700 per sample, and routinely takes 3-10 days to get a result. Although ELISA methods require only one to four hours to perform and cost one-tenth as much,

they still are not ideal for truck-side testing. Another form of immunoassay, the immunochromatographic strip test, has been developed to meet the performance specifications required for testing agbiotech crops in the field (see box, "Strip Tests" for AgBiotech Proteins). These tests use the same technology as the home pregnancy test. They are very easy to use, cost less than \$10 per test, take 5-10 minutes to complete, and can be performed truck-side.

For the foreseeable future, agbiotech crops will coexist with conventional varieties, and the world will have to find ways to deal with both. Coupling the advent of agbiotech crops with consumer-valued traits will necessitate that systems and strategies capable of preserving the identity of these crops be in place to capture the added value; work that is done now to develop these systems will facilitate commercialization in the future. Although detection

technology is available for most agbiotech crops, implementation of testing lags behind production and regulations, leaving the entire industry in a quandary on how to proceed. In the near term, it seems likely that solutions will comprise elements of identity preservation, incorporating screening tests at critical control points throughout the distribution system along with limited, standardized testing at major points of export and import References

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- James W. Stave is vice president of research and development for Strategic Diagnostics Inc. (Newark, DE). Donald Durandetta is a product manager for

Diagnostics Inc. (Newark, DE). Donald Durandetta is a product manager for agricultural products for Strategic Diagnostics Inc. (Newark, DE). Comments and questions for the author can be addressed to the Editorial Officeby e-mail at tcaw@acs.org, by fax at 202-776-8166 or by post at 1155 16th Street, NW; Washington, DC 20036.

RESEARCHERS AIM TO TAKE CONE OUT OF CONIFEROUS: TREE PROJECT LATEST IN GENETIC MODIFICATION
June 20, 2000
The Ottawa Citizen
News
A8
Business

Canadian government scientists are, according to this story, testing the first of 250 genetically engineered spruce, part of their research into the

Colin Grey

newest frontier of genetic modification trees.

The story says that the government, anticipating that genetically modified trees could start being used within the industry within five to 10 years, has been working in a little-known project to prevent modified trees from interbreeding with wild ones.

In other words, the research's eerily futuristic goal is coniferous trees without cones.

Bob Rutledge, a researcher with the Canadian Forest Service, was quoted as saying, ``We're trying to coax the tree into not flowering. If we were to plant

genetically engineered trees out in the environment, we don't want them breeding with wild populations.''

Government researchers have also been looking at other aspects of gene research to increase their knowledge of trees on a molecular level, so as to allow for better regulation of modified trees when the need arises. The story adds that the field tests at the Lauren-tian Forestry Centre involve 150 spruce trees engineered to be pest-resistant. One hundred of them have `marker' genes, which researchers will trace in order to find out what happens to implanted genes as a tree grows.

Trees take longer to grow and are generally harvested from natural forests. The backlash against genetically modified crops in the past several years has forestry companies gun-shy about getting involved.

Pierre Charest, director of the Forest Service's science division, was quoted as saying, `If you were to introduce a gene that could have some potential impact if it spread into a natural forest, then you wouldn't want that to happen. So

one potential scenario would be to have trees that wouldn't have pollen or seeds.''

Apart from the government's, there is only one other field test in Canada. Alberta-Pacific Forest Industries Inc. is running a field test of hybrid poplars, resistant to herbicides.

In B.C., three nurseries were attacked in the past year by environmentalists, who wrongly believed they contained genetically modified trees.

In the U.S., university labs at Washington University and Oregon State University are doing active research. Arborgen, a joint venture of three multinational forestry companies, has just formed to work on genetically modified trees.

BRAZIL BLOCKS MORE ARGENTINE CORN AS GM-SUSPECT June 20, 2000

Reuters

Jeremy Smith

RIO DE JANEIRO -- Brazil has, according to officials cited in this story, temporarily banned the entry of another cargo of Argentine corn while experts determine whether the grain is genetically modified and thus contravenes local law.

The story says that the government of Brazil's northern state of Pernambuco issued a ruling this week which prohibits the unloading of 38,000 tonnes of corn shipped by the Uruguayan subsidiary of private U.S. grain giant Cargill.

A spokeswoman at the Pernambuco state agriculture secretariat was quoted as saying, "It's been forbidden to unload it and we don't know yet if it's transgenic. It's still being tested."

The vessel carrying the corn arrived a few days ago in the port of Pernambuco's state capital Recife.

The corn was purchased for use as animal feed by the Brazilian poultry

industry, which along with the local pig industry, is the country's largest corn consumer.

Brazil outlaws genetically altered grains while neighboring Argentina, its largest trading partner and ally in the Mercosur bloc, is the world's second producer of the super crops -- particularly corn and soybeans.

BRAZIL MAY GROW GM GRAIN IF PRICE RIGHT

June 20, 2000

Reuters

Jeremy Smith

RIO DE JANEIRO -- Agricultural giant Brazil, one of the last bastions against genetic modification, would, according to the Agriculture Minister, happily grow GM grains and label them for any consumer if market conditions dictated,.

The story says that Brazil, the world's second largest soybean producer, is the last major competitor to the U.S. not to follow the North American country down the transgenic trail as its government, currently outlaws the growing of genetically altered grains.

Agriculture Minister Marcus Vinicius Pratini de Moraes was cited as saying that all that could change if Brazil were to see improved overseas demand for transgenic grains with a correspondingly higher return for farmers, adding, "We will be able to provide the market with whatever the market wants to buy, and pay for. If Europe wants to buy non-transgenics and will pay for them, then we'll produce what Europe wants. We are looking at the bio-safety considerations...and we are asking the markets their opinions. We will produce whatever the market wants to buy. And we will be very cautious and very careful in the labeling of what we produce."

The story notes that Brazil is the hemisphere's only major agriculture producer to outlaw GM crops, a policy which is not popular with all farmers in the country's key southern grain states, where authorities have in the past ripped up "illegal" plantings.

With long-term GM advocate Argentina notching up savings on costly weed killers, a thriving black market in smuggled GM seeds has sprung up across the border in neighbouring Brazil, where jealous growers itch to buy up the lab-enhanced seeds.

GM SALES TO BE CHECKED AGAINST DISEASES

June 20, 2000

The UK Times/ The Electronic Telegraph

Valerie Elliott, Consumer Editor

http://www.the-times.co.uk/news/pages/Times/timconcon01001.html
The UK Food Standards Agency is, according to this story, to monitor
shopping habits as part of research into the possible impact of genetically
modified and other unusual food products on human health.

The testing is to start in July, using supermarket loyalty cards, which are linked to postcodes and can be used to establish buying habits and matched to diseases reported to the Public Health Laboratory. If card data is not available,

researchers will analyse regional food sales.

They are to check the sales data for food containing GM soya and maize which could be contained in oils and processed foods. It is also expected that there will be tests on the effect of ingredients developed using GM technology such as

lecithin, a solidifier used in the manufacture of chocolate, and chymosin, a rennet used in vegetarian cheeses and pizzas.

Consumption patterns will be linked to such data as the number of birth defects or increased cases of cancer, diabetes and other diseases. Any health benefit from eating the food will also be assessed. It is likely to take at least 18 months to see if a model can be set up that can act as an "early warning" system for foods that affect human heal th.

Spot-checks on food sold in supermarkets as GM-free are also to begin in the autumn. Agency officials want to check whether supermarket labels and information on hotel and restaurant menus is accurate.

MODIFIED FOOD REGULATOR GETS SHARP TEETH

June 21, 2000 Sydney Morning Herald James Woodford, Science Writer http://www.smh.com.au/news/0006/21/national/national06.html The first Australian Federal statutory body authorised to approve the introduction of genetically modified organisms will, according to this story, have similar powers to the Federal Police. A briefing paper on legislation which will be presented to Parliament this week was cited as saying that the proposed Gene Technology Regulator will be able to appoint inspectors with powers to investigate breaches of the new law, adding, "[The regulator will] have enforcement powers which include the ability to issue directions, cancel or suspend approvals, seek injunctions and make reports directly to Federal Parliament. The legislation also imposes stringent penalties in the case of a breach of the legislation of up to \$1.1 million for corporations." The regulator would be able to order independent research into any proposals that come before it and a range of monitoring powers. The story says that at present the interim office of Gene Technology Regulator relies on the goodwill of companies, and none is under any legal obligation to comply with the recommendations of a non-statutory body, the Genetic Manipulation Advisory Committee. The head of the interim office, Ms Liz Cain, was cited as saying the new regime would enable the public to feel more confident about gene technology. Three committees - policy, scientific and ethical - will be established as will a public database of all genetically modified organisms in Australia.

WHEN THE LABEL FITS
June 21, 2000
The Sydney Morning Herald
http://www.smh.com.au/news/0006/21/html/letters.html
D. Davie, Annandale writes that Mr Howard wants "an exemption from labelling
for foods with less than 1 per cent concentration of GM-altered
ingredients" (Herald, June 19). Here is another percentage:
90 per cent of Australians want all genetically modified foods

labelled - that includes refined sugars and oils which use GM enzymes in processing.

Annandale says that the unfortunate 37 people who died, and the 1,548 who were permanently disabled, from taking genetically engineered L-tryptophan in 1989 consumed only 0.1 per cent GM material in the final product.

If Mr Howard is bowing to pressure from the US Government to accept the GM food that the rest of the world is rejecting, then our PM should be aware that the United States Food and Drug Administration (FDA) is the subject of a lawsuit for a cover-up on GM food.

FDA documents, revealed during the trial, showed that stomach lesions occurred in rats fed GM tomatoes.

C.M. Woodley of Bondi writes that the term genetically modified was coined by the biotechnology companies. The true term is genetically engineered. To engineer a crop biotechnicians blast the information of another plant or animal into the genetic make-up of the host plant.

This is, says Woodley, a hit-and-miss procedure: where the new gene ends up in relation to other genes in the plant is pure chance. To identify if the gene has been successfully transferred to the host plant, a marker is used. That marker is bacteria, but not just any bacteria, antibiotic-resistant bacteria.

Bacteria are in our gut, in soil, plants and carried in the air. Their ability to mutate and multiply is why we are facing the very real threat of the present armoury of antibiotics that we use being rendered useless.

Genetic engineering has the propensity to change the whole biodiversity of nature, to increase the incidence of cancer and create antibiotic resistance.

EARLY-WARNING SYSTEM TO DETECT SPREAD OF ASIATIC CITRUS CANKER June 20, 2000

ARS News Service

Agricultural Research Service, USDA

Jes™s Garcla, (301) 504-1627, jgarcia@ars-grin.gov

The thunderstorms that often rage during sultry summertime afternoons in subtropical Florida have exacerbated the spread of Asiatic citrus canker (ACC). This bacterial disease now threatens the state's multibillion dollar citrus industry.

Scientists with the Agricultural Research Service's U.S. Horticulture Research Laboratory in Ft. Pierce, Fla., led by plant pathologist Tim Gottwald, have developed a new strategy for detecting ACC infestations. The disease primarily spread by wind- driven rain is thought to have arrived in south Florida in 1992 or 1993. It has spread to more than 1,200 square miles of citrus-producing areas around the state.

ACC causes brown blemishes on citrus leaves, twigs and fruit, resulting in fruit drop, loss of yields and quality. This leads to a loss of local, national and international markets due to quarantine restrictions. The new early-warning system for ACC will be used in a statewide survey to detect the disease. Gottwald's study determined that a 1,900-foot zone is required to limit further spread of the disease. The study also recommended that a "sentinel tree grid" be established to detect and prevent the further spread of ACC into major grapefruit production areas. Florida produces 75 percent of U.S. citrus. Worldwide, the United States is second to Brazil in citrus fruit production.

The 15-mile wide by 20-mile long sentinel tree grid comprises 144 existing dooryard trees of susceptible cultivars arranged in a 12-by-12 pattern covering each square mile of the area directly north of the Miami Dade and Broward county infestation. Trees within the grid are 450 feet apart. By making a visual survey of the grid every 30 days, scientists will be able to see if any new ACC outbreaks have occurred after eradication of the initial outbreak.

These findings have led to an increase in the ACC eradication budget to \$175 million, with an additional \$40 million for payments to growers hit by the disease.

ARS is the chief research agency of the U.S. Department of Agriculture.

BUG THREATENS CANOLA; CABBAGE SEED POD WEEVIL COULD WIPE OUT CROP IN THE WEST

June 20, 2000

The Edmonton Sun

News

page 5

Scott Pattison

Alberta Agriculture has, according to this story, declared a state of emergency on an evil weevil that could wipe out Western Canada's canola crop.

Lloyd Dosdall of Alberta Agriculture's pest prevention and management unit was quoted as saying, "This is the greatest threat Canada's canola crop has ever experienced. We're experiencing a massive outbreak, more than 14 times the number found last year. It has the potential of wiping out Western Canada's canola crop."

Known as the cabbage seed pod weevil, this is an insect without any predators. As a result, says Dosdall, the evil weevil has already crossed into southwestern Saskatchewan, fuelling concerns it could eventually mow down Manitoba's canola crop, dealing yet another financial blow to the Canadian farmer.

"We didn't realize the enormity of the situation last year," Dosdall said. Agricultural pest control specialists are struggling to find a solution to the ash-grey-coloured critter which was accidentally brought into the United States from Europe in 1995 and then migrated north into Alberta.

Alberta's capola crop generated \$600 million in revenue last year, says

Alberta's canola crop generated \$600 million in revenue last year, says Alberta Canola Board general manager Ward Toma.

The weevil represents an epidemic for Canada's agricultural community, Toma said.

MILKWEED ORDER THREATENS MONARCHS: HOMEOWNERS TOLD TO KILL 'NOXIOUS WEEDS' June 20, 2000

The Ottawa Citizen

City

B1 / Front

News

Tom Spears

Ottawa is, according to this story, ordering its residents to destroy ``noxious weeds,'' and has taken special aim at the milkweed, a plant vital to survival of the monarch butterfly.

Rip 'em all out, warns a newspaper ad from the city, or weed inspectors may

enter your property, destroy the plants and send you a bill. Milkweed is the only place that offers monarch butterflies food and a place to lay eggs.

Monarchs are on Canada's Endangered Species List. They make a heroic annual migration to Mexico and back, farther than many migratory birds fly. Beyond that, they're probably our best known and most loved insectobig, bright butterflies covered in black and orange.

The noxious weed order made Judi Lian see red. She phoned Ottawa City Hall, where a weed inspector told her the city only acts on the threat if it has complaints. So far this year it hasn't had any milkweed complaints. Ms. Lian phoned the Citizen to complain, stating, ``It's too stupid to go unchallenged.''

On the one hand, she doesn't think people will really go charging out to attack milkweeds because of the small print at the bottom of a city hall advertisement.

Ottawa Councillor Richard Cannings was cited as saying that people shouldn't blame the city, since it's bound to enforce provincial law, in this case the Weed Control Act. That act lays out about two dozen ``noxious weeds'' that property owners must kill, including poison ivy, ragweed and milkweed. Mr. Cannings is exploring some sort of motion to let the milkweed live in areas where it's doing no harm. Milkweed is mainly an agricultural weed, and Mr. Cannings said its presence should be tolerated in the city. There's even a ``monarch garden''(an area where milkweed is actively cultivated(somewhere in Mr. Cannings's Rideau ward. He won't say where in case someone sends in the weed inspectors.

INNOVATECH GRAND MONTRÉAL AND FONDACTION INVEST IN NEW ENVIRONMENT-FRIENDLY BIOLOGICAL INSECTICIDES

June 20, 2000

Canada NewsWire

http://www.newswire.ca/releases/June2000/20/c6990.html
MONTREAL -- Innovatech Grand Montreal, a venture capital
firm specializing in high technology, and Fondaction, the CSN¹s development
fund for cooperation and employment, are investing \$1 Million and \$300,000
respectively in AFA Environment Inc. of Montreal. This company conducts
research and development into environment-friendly biological insecticides.
The investment will enable AFA Environment to create a dozen new jobs and
develop new products such as biological controls for spruce budworm.
With a dozen specialized employees and a team of scientists representing
close to 40 years of combined experience, AFA develops biological
insecticides

for agricultural, aquatic and forestry use.

Destructive pests such as the spruce budworm are making a strong comeback, and AFA Environment products play an important role in taking the counteroffensive without endangering the environment. Fondaction is proud to invest in a company that represents one of its primary areas of interest, environmental protection.

Created in 1996, the CSN workers¹ fund today represents over 21,000 shareholders and total assets of over \$100 million. To date, Fondaction has invested over \$30 million in Quebec companies, specifically those involved in

a participative management process or the social economy (self-controlled, cooperatives or others) and those active in environmental protection (www.fondaction.com).

Innovatech Grand Montreal is a venture-capital firm that specializes in financing technological innovations in a company's start-up phase or at the

time of technology transfer. Innovatech focuses its activities in sectors recognized for their dynamism: information technologies, telecommunications, health sciences and new industrial technologies. It works closely with the companies in its portfolio, acting as a business partner from start-up to success (www.innovatech.qc.ca).

For further information: Gerald A. Lefebvre, Innovatech Grand Montreal, (514) 845-2257 or (514) 864-2929; Serge Lareault, Fondaction, (514) 525-4673

NATURAL RESOURCES CONSERVATION SERVICE TASK FORCE ON AGRICULTURAL AIR QUALITY June 20, 2000 Federal Register (Volume 65, Number 119) [Notices] [Page 38241-38242] [DOCID:fr20jn00-35] http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2000 register&doci d = 00 - 15491 - filedDEPARTMENT OF AGRICULTURE Natural Resources Conservation Service Task Force on Agricultural Air Quality AGENCY: Natural Resources Conservation Service (NRCS). ACTION: Notice of meeting. SUMMARY: The Task Force on Agricultural Air Quality will meet for the third time in FY 2000. Special emphasis will be placed on obtaining a greater about understanding the relationship between agricultural production and air quality. The meeting is open to the public. DATES: The meeting will convene Tuesday, July 18, 2000 at 9 a.m. and continue until 4 p.m. The meeting will resume Wednesday, July 19, 2000 from 9 a.m. to 4 p.m. Written material and requests to make oral presentations should reach the Natural Resources Conservation Service, at the address below, on or before July 12, 2000. ADDRESSES: The meeting will be held at the Hall of States, 444 Capitol Street NW, Rooms 333/335, Washington, DC 20001, telephone (202) 624-8670/fax (202) 624-8588. Written material and requests to make oral presentations should be sent to George Bluhm, University of California, Land, Air, and Water Resources, 151 Hoagland Hall, Davis, CA 95616-6827. FOR FURTHER INFORMATION CONTACT: Questions or comments should be directed to George Bluhm, Designated Federal Official, telephone (530) 752-1018, fax (530) 752-1552, email bluhm@crocker.ucdavis.edu.

IMPORTATION OF GYPSY MOTH HOST MATERIAL FROM CANADA
June 20, 2000
Federal Register (Volume 65, Number 119)
[Rules and Regulations]
[Page 38171-38177]
[DOCID:fr20jn00-1]
http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2000_register&docid=00-15470-filed
Rules and Regulations
Federal Register
This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. 98-110-2]

RIN 0579-AB11

Importation of Gypsy Moth Host Material From Canada

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are adopting as a final rule, with minor changes discussed in this document, an interim rule that established regulations for the importation into the United States of gypsy moth host materials from Canada due to infestations of gypsy moth in the Provinces of British Columbia, New Brunswick, Nova Scotia, Ontario, and Quebec. The rule requires trees without roots (e.g., Christmas trees), trees with roots, shrubs with roots and persistent woody stems, logs and pulpwood with bark attached, outdoor household articles, and mobile homes and their associated equipment to meet specified certification or destination requirements if they are intended to be moved into or through areas of the United States that are not infested with gypsy moth. This action is necessary to prevent the introduction of gypsy moth into noninfested areas of the United States.

EFFECTIVE DATE: June 20, 2000.

FOR FURTHER INFORMATION CONTACT: Ms. Coanne O'Hern, Operations Officer, Invasive Species and Pest Management, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737-1236; (301) 734-8247.

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For more information about the Agnet research program, please contact: Dr. Douglas Powell

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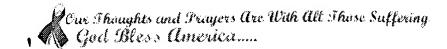
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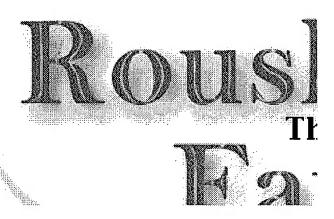
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Put To The ? No Standards Exist For Gene



September, 2000 By Greg D. Horstmeier FarmJournal.com

A genetic purity test should be the ultimate measure of whether an identity-preserved (IP) grains program before those grain testing systems pass the test. Take testing nom-genetically modified (GM) seeds. "Th material allowed (to) still qualify as no-GM." says Don Durandetta, marketing manager for Strategic Diagn seed, and plans additional test kits for many Bt corn products.



"Labs in the U.S. have tested grain and found it clean," Durandetta notes. "Then the grain arrives in Euro be (a difference) in the tests."

Testers use three basic GM test methods. Polymerase Chain Reaction (PCR) tests search for a trait's DN for the proteins the trait produces. Bioassays can be used for traits such as herbicide resistance. Seeds have the resistant trait.



"We know PCR and ELISA tests can accurately judge GM content of a sample," says Tim Gutormson, p sample is an accurate representative of the load."

"The problem is the lack of globally accepted standards for minimum or maximum trait levels. Until such t sampling methods, Gutormson says."



Development of tests for future IP seeds is also moving more slowly than many testers prefer. "Companie Syajgro of the Indiana Crop Improvement Association, "without access to that information, it's difficult to d seed company could have it's hybrids contaminated by another's experimental trait and not know it for ye

Biotech companies acknowledge the issue of protecting secrets vs. working with third parties to develop t for reluctance. "Results from one company's PCR test can vary significantly from another company's PC USDA is working on a validation and certification process, she says. Until then, it's unlikely a biotech com

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